APPENDIX A

COMMENTS
on the Waste Minimization Prioritization Tool

TOPIC OUTLINE

COMMENTS

I. Technical Aspects of Waste Minimization Prioritization Tool Software

A. Chemical Scoring Based on Persistence, Bioaccumulation, Toxicity, and Mass

1. Adherence to Risk Assessment Paradigm; Weighting and Aggregation of Scores

a. Adding Human Health and Ecological Risk Potential Scores vs. Taking Higher of the Two

- Data quality is of utmost importance in order for WMPT to be used for any type of priority setting. In order to account for data quality, separate lists should be generated for ecological and human potential concern. For each chemical, the ranking should be separately based on the score received by the highest quality data in each category. Ranking data quality in this way would provide an incentive for users to provide better quality data. There would need to be a mechanism within EPA to review submitted data that challenges the data used in WMPT. (S1i:37,38)

- This approach is not consistent with the Agency's policies regarding risk assessment and risk management. For example, the listing approach has no procedure to properly evaluate exposures to human and ecological receptors. EPA's work in tiered risk assessment and risk management should be used in the development of waste minimization goals. (D30:3)

- EPA should separate human health and ecological risk potential in the development of the final WMPT in order to take data sufficiency and data uncertainty into account, and to allow separate prioritization of high risk in either category even when data is inadequate in the other. EPA might want to divide each group into likely, probable, suspected classifications for any list that might be developed (e.g., the PCL). (S1i:9)

- Ecological risk assessments are very different from human health risk assessments, and therefore, it is not correct to combine the ecological and human health risk potential scores to generate an overall chemical score. Additional input on this issue should be solicited from people involved in ecological risk assessments. (S1s:27)

- The ecological risk potential score should be separate from the human health risk potential score because if a chemical had a high human health risk potential score but a low ecological risk potential score, the overall score would not be high enough to accurately reflect the hazard. (S1s:28)

- It might be better to use the higher of the ecological and human health risk potential scores to generate the overall score, rather than to combine them. This is more conservative and more defensible. Use of both human health and ecological risk potential scores is similar to "comparing apples to oranges." (S1s:28)

- Create separate rankings for ecological risk potential and human health risk potential; assign separate data quality scores to each chemical for each risk potential; and, for purposes of ranking priorities, chose either the human health risk potential score or the ecological risk potential score, based on the better associated data quality (i.e., choose the risk potential score associated with the higher quality data). If the data quality is judged to be the same, the higher risk potential score should be used. The following matrix shows the decision criteria.:

	Human Health Risk Potential (score)	Ecological Risk Potential (score)
High Quality Data		
Low Quality Data		

The reasons for this alternative include the following: data quality is of utmost importance in prioritizing chemicals for waste minimization purposes; this formulation avoids the problem of double counting persistence and bioaccumulation because the priority ranking is based only on the persistence and bioaccumulation from either human health risk potential or ecological risk potential; and it separates the human health risk potential from the ecological risk potential. (S1i:35)

- Ecological and human health risk potential scores cannot be compared, even when a binning system is used. (S1i:35,36)

- In calculating the overall PBT score for each chemical, WMPT adds the scores for human health risk potential and ecological risk potential. This methodology, in effect, ranks chemicals based upon the average of their ecological and health risk potential scores, thereby lowering the relative ranking of chemicals that pose high levels of ecological *or* human health risk, but not both. Further, the only chemicals receiving overall scores are those chemicals that have complete human and ecological toxicity data. EPA should evaluate ranking chemicals based upon their overall score, the higher of their human health risk potential and ecological risk potential scores, or their human or ecological risk potential scores independent of each other. (E1:6,11)

- Ecological and human health risks assessment screening components should be kept separate. The paradigms are quite different as are the dose-response relationships between the chemical and human/non-human receptors. (D55:2)

- Combining human and ecological risk scores into a composite score "dampens" the differences between the two, and provides less information for the risk manager to make effective decisions about prioritizing strategies to minimize toxic wastes. It would be much more useful and informative to know immediately whether a material poses a human or ecological risk with respect to how to manage that risk (e.g., a material not particularly toxic to humans, but very toxic to fish could be redirected from a wastewater stream to a more easily confined waste stream; conversely, chemicals not very toxic to aquatic organisms could be directed to a highly diluted water effluent). (D29:4; D31:11)

b. Counting Persistence and Bioaccumulation Values Twice

- It would be much better to have a toxicity rating which evaluates potential hazards to both human and aquatic life, a persistence/bioaccumulation rating, and an exposure potential rating (based on released volumes). A weight may be assigned if it is decided that equal weighting should not be given to toxicity, persistence and exposure potential. (D75:15-16)

- Not only does the WMPT utilize modeled data for persistence and bioaccumulation when good quality measured data are available, it gives double weight to the same inadequate data by using the same values in human health risk potential and ecological risk potential. This double weighting can unjustly result in a chemical being considered as persistent/bioaccumulative problem when it is not. Additionally, this approach ignores factors such as the physical and chemical properties of chemicals and fate and degradation processes. (D75:16)

- The WMPT inappropriately weights the persistence factor in the overall chemical score. (D43:i)

- Double counting the persistence score in a chemical's overall score yields particularly unfair results for metals because the persistence score is a default value that is highly conservative. Therefore, metals are treated differently from other chemicals. (D43:3-4,5)

- The six components used in the WMPT algorithm for scoring purposes provide a misleading score for copper. The algorithm evaluates: human toxicity, persistence and bioaccumulation and ecological toxicity, persistence and

bioaccumulation. Because copper, as a metal, is not biodegradable, it receives the highest score of three for both human and ecological persistence, in effect double-counting, and leading to a skewed prioritization of copper. (D61:2)

- Persistence and bioaccumulation are used twice in calculating the score for a chemical. The Pulp Chemicals Association believes this practice overstates the importance of these elements with respect to overall risk. It also compounds the effect of the low quality data the EPA is using to complete the model. EPA has not rated the quality of data for Persistence (high, medium, low etc.) as it has done with the other elements of the WMPT. (D60:2)

- There is no reason to count persistence and bioaccumulation data more than once, especially since this is some of the least prevalent or scientifically compelling data in the tool. Counting them only once does not significantly change the distribution of scored chemicals, though it does tend to eliminate the "elongation" of the upper end of the curve (see exhibit, D64:4). The same chemicals are in the top 25% in both methods, but the range of scores is fewer if you count persistence and bioaccumulation only once. If greater differentiation is required, increase the number of gradations within each category (for example, we use a scale of 1 to 5, rather than 1 to 3, in each of our categories.) There is one important consideration, however; double counting persistence and bioaccumulation effects the importance of the mass factor and can moderately alter the final outcome, depending on the size of the mass score. For example, in two hypothetical cases with the same chemicals in the same percentages of the whole, but the first list is for a waste stream measured in millions of pounds per year and the second list is in thousands of pounds per year, the priority order of the chemicals given is different in each case. Which of is the correct one to pursue? The results imply that the smaller your business, the greater the priority you should give to small amounts (1.78 pounds) of highly scored chemicals. (D64:4,5)

- The persistence and bioaccumulation scores for all chemicals are counted twice, under the human health risk potential and under the ecological risk potential, compounding any error in the chemical-specific data. The contribution from persistence and bioaccumulation should be used once in the overall chemical score. (D35:5; D38:1)

- In the Overall Chemical Score, Persistence and Bioaccumulation have twice the weight of the toxicity scores in determining the magnitude of the score. This arrangement puts undue emphasis on Persistence and Bioaccumulation. Instead the OCS should only add Persistence and Bioaccumulation once. (D30:5; D34:2)

- The inaccurate persistence score assigned to methyl chloride is compounded by the fact that the WMPT double-counts persistence and bioaccumulation scores. As a result, the final rankings are skewed such that a high score in either of these categories has a disproportionate impact on the overall chemical score. Because of the inaccurate and double-counted persistence score, methyl chloride's overall score of 9 has 2 additional and unwarranted points. (D53:9)

- The WMPT uses a scoring algorithm that double counts persistence and bioaccumulation, thereby exaggerating any errors in scoring those factors. (D21:5)

- WMPT "double-counts" persistence and bioaccumulation, as well as mass, thereby outweighing the exposure potential and compounding any error in the chemical-specific data. For example, the inaccurate persistence and bioaccumulation scores for trichlorophenylsilane add an additional unmerited 4 points out of a total of 11—or 36% of the entire score. This redundancy should be eliminated by (I) combining the human and ecotoxicity elements into one toxicity hazard factor and (ii) calculating separately the exposure potential. (D49:3, 13)

- Double-counting is particularly troublesome because more persistence scores are derived from EPA estimates rather than actual data, and are based on an evaluation of only a limited number of degradation pathways.

Likewise, most bioaccumulation scores also are derived from predicted bioaccumulation values rather than actual data. (D49:2, 14)

- Because the identical persistence and bioaccumulation scores are used for both human health and ecological evaluation (i.e., they are double counted and, in fact, make up 12 of the total possible 18 points), there are, in effect, only 9 degrees of discrimination among the 879 chemicals on the PCL with the concomitant 2:1 weighting of persistence and bioaccumulation relative to toxicity. (D31:11)

- The scoring system is designed to give too much weight to the bioaccumulation and persistence surrogates for exposure relative to the toxicity scores for human and ecological risk. Because bioaccumulation and persistence are intrinsic chemical properties, their values will not change for the purposes of estimating human or ecological risk. Entering them twice in the algorithm double counts their value. Therefore, the apparent relative risk of compounds that are bioaccumulative or persistent is inflated. The principle underlying the emphasis for bioaccumulation and persistence as exposure surrogates is well intentioned, but incompletely stated. However, it is the potential for *bioavailability*, not just bioaccumulation and persistence, that determines the degree of risk. The scoring system has the potential of artificially inflating the potential risk of some toxicants relative to others. (D31:12,13)

- EPA should revise the scoring system to delete the double counting of persistence and bioaccumulation. The scoring system is designed to give too much weight to the bioaccumulation and persistence surrogates for exposure relative to the toxicity scores for human and ecological risk. Because bioaccumulation and persistence are intrinsic chemical properties, their values will not change for the purposes of estimating human or ecological risk. Entering them twice in the algorithm double counts their value. Therefore, the apparent relative risk of compounds that are bioaccumulative or persistent is inflated. The principle underlying the emphasis for bioaccumulation and persistence as exposure surrogates is well intentioned, but incompletely stated. However, it is the potential for *bioavailability*, not just bioaccumulation and persistence, that determines the degree of risk. Bioaccumulation implies that there is likely to be uptake but does not necessarily equate to an exposure. The scoring system has the potential of artificially inflating the potential risk of some toxicants relative to others. (D29:cover2,5)

- Environmental risk is largely a function of exposure and toxicity. Persistence and bioaccumulation are both good proxies for measuring the duration of a chemical exposure. Whether you are assessing a chemical's human health risk potential or its ecological risk potential, these two measures remain constant. WMPT, however, treats these measures as variables and, as a result, "double-counts" a chemical's tendency to persist (P) and bioaccumulate (B) even though the chemical's relative P and B rankings remain the same whether you are looking at the human health risk potential or the ecological risk potential. This double counting results in an overestimation of P and B factors vis-a-vis a chemical's toxicity ranking (T), resulting in a higher and, therefore, "worse" score for chemicals that are very persistent or bioaccumulative—regardless of their toxicity ranking, which is the real driver of a chemical's environmental risk. (D54:2)

- EPA should revise its scoring algorithm so that it does not double count persistence and bioaccumulation; the current algorithm does this by assessing these characteristics for both ecological and human toxicity. (D27:78)

- The WMPT counts persistence and bioaccumulation twice and, therefore, focuses on six scoring components rather than just four. (D9:3; D10:2-3)

- In the case of naturally occurring elements, double-counting of the persistence factor is scientifically misleading with regard to a substance's risk potential. Such treatment of metals skews the rankings of the WMPT and Draft PCL and renders them inappropriate for the purpose of establishing a realistic comparison of chemicals according to their risk potentials. (D9:3; D10:3)

- The WMPT algorithm double counts bioaccumulation and persistence since they are counted both under ecological and human health risk potential. Most chemicals would be persistent and bioaccumulate both in humans and in the environment, and they are scored identically. Therefore, the tool gives bioaccumulation and persistence too much weight relative to toxicity. The overweighing occurs as a direct result of aggregating the human health risk potential and the ecological risk potential. One or the other score should be removed from the model. (S1i:7; S1s:26)

- The WMPT scoring algorithm should be rearranged to correctly incorporate persistence and bioaccumulation. Persistence and bioaccumulation should both be included as separate factors because some chemicals are persistent and not bioaccumulative, and some are bioaccumulative but not persistent. Persistence and bioaccumulation, however, should not be included twice. To avoid double counting of persistence and bioaccumulation, add the human toxicity score to the human and ecological bioaccumulation and persistence scores and to the ecological toxicity score to address the issue of double counting persistence and bioaccumulation. Note, however, that human and ecological bioaccumulation and persistence scores may not always be the same. (S1s:27,34)

- The scoring algorithm should be restructured so that persistence and bioaccumulation are not double counted. (S1s:28, 32)

- WMPT calculates both human health risk potential scores and ecological risk potential scores by adding identical persistence and bioaccumulation values. This creates an overall score that "double counts" persistence and bioaccumulation values. This is appropriate because both ecological toxicity and human toxicity values are added (i.e., toxicity also is counted twice). (E1:7)

- EPA should evaluate whether the chemical properties of bioaccumulation and persistence need to be included twice in the algorithm. The tool loosely follows the risk assessment paradigm in that it assigns both bioaccumulative and persistence qualities of a chemical as representative of the exposure potential. A chemicals exposure potential is the same whether it is considered from the viewpoint of an ecological or human receptor. Therefore, they do not need to be included twice. The human and ecological exposure should be combined in the model such that the overall scores will range from 4-12, with the exception of the mass calculations. The only reason for separating these two scores is to mimic a risk assessment. However, the WMPT algorithm is too loosely related to the risk assessment paradigm to have to rigidly adhere to the paradigm. Also, combining the scores simplifies the algorithm. (D55:cover2,2,3)

c. Double-Weighting of Exposure Relative to Toxicity

- We believe the WMPT methodology is unduly arbitrary and significantly flawed, particularly as it applies to metals. We do not understand, for example, why exposure potential should be weighted twice as heavily (once for persistence and once for bioaccumulation) as toxicity. (D56:2)

- WMPT "double-counts" persistence and bioaccumulation, as well as mass, thereby outweighing the exposure potential and compounding any error in the chemical-specific data. This redundancy should be eliminated by (I) combining the human and ecotoxicity elements into one toxicity hazard factor and (ii) calculating separately the exposure potential. (D49:3)

- To determine if the impact of P, B, and T weighting is critical, EPA should perform a series of tests/analyses giving different and equal weights to P, B, and T and compare the outcome of the overall chemical rankings. If the scoring and ranking of chemicals change dramatically, then the algorithm should be re-scaled accordingly. (S1e:15)

- Although the WMPT documentation states that the scoring algorithm closely follows the risk assessment paradigm, there is a discrepancy between the risk assessment paradigm and the WMPT scoring algorithm. In the WMPT scoring algorithm, a chemical's persistence is taken into account by including a separate factor for persistence. In the risk assessment paradigm, however, a chemical's persistence is captured by another (not separate) factor, rather than as a separate factor specifically for persistence. Therefore, the WMPT has added persistence to the paradigm. While this is not necessarily wrong, it is important to clarify in the documentation that persistence has been added to the risk assessment paradigm as a measure of exposure. (S1s:23)

- There are only 9 degrees of discrimination among the 879 chemicals on the PCL with the concomitant 2:1 weighting of persistence and bioaccumulation relative to toxicity. Toxicity should not have a lower weighting, and may indeed, deserve a higher weighting given that persistence and bioaccumulation are poor surrogates for measures of exposure. (D31:11)

- Modify the model so that toxicity receives equal weighting (increase to 50%) to exposure (persistence and bioaccumulation are weighted 50% when P and B are combined to estimate exposure). (D32:cover1)

- PBT are reasonable criteria, but weighing all three equally overweighs exposure relative to toxicity. (D32:4)

- The potential health hazard associated with severe sensory irritants or poisons remains inadequately evaluated and prioritized. For example, mustard gas is given an overall score of 11, which is below silver, and cyanide and potassium cyanide are assigned scores of 9, which are relatively low ranks in WMPT. On an acute basis, these materials are highly hazardous and the current methodology overweighs the value of persistence and bioaccumulation at the expense of underestimating the potential human health effects of severe acute toxicants and poisons. (D32:4)

- In calculating the overall chemical score, the WMPT algorithm, as currently structured, appears to give more weight to exposure than to toxicity. Under the current algorithm, a chemical can receive a toxicity score that ranges from 1-3 and an exposure score that ranges from 2 - 6. However, equal weight should be given to both toxicity and exposure. For example, a chemical should receive a toxicity and exposure score ranging from 1- 6. The current algorithm may not be able to raise a chemical high in toxicity to the top of the list. (S1e:14)

- The WMPT algorithm should follow the risk assessment model/paradigm, and therefore, equal weight should be given to exposure and toxicity. (S1e:14)

- Identify OSW's policy on assigning weights to exposure and toxicity, and modify WMPT to reflect that policy. Additionally, this policy should be clearly articulated in the WMPT user's guide and system documentation. (S1e:15)

- Exposure scores can range from 2 to 6 while toxicity scores range from 1 to 3. This appears to give more weight to exposure potential than toxicity. It would be useful to see if this has any effect on the rankings. EPA should run a series of tests to see how chemicals would rank if exposure and toxicity were equally weighted. The Agency should compare the results to the ranking of an actual risk assessment. (S1e:34)

- Since the values for persistence and bioaccumulation are the same for each risk potential, it give those two factors added weight over toxicity. It seems that a more useful format would be three charts: (1) overall priority, which calculates scores based on P, B, human toxicity, and ecological toxicity, (2) human health priority, which calculates scores based on P, B, and human toxicity, and (3) ecological priority, which calculates scores based on P, B, and ecological toxicity. (D55:3)

d. Weighting Human vs. Ecological Concerns

- We believe the WMPT methodology is unduly arbitrary and significantly flawed, particularly as it applies to metals. We do not understand, for example, why ecological toxicity (dominated by effects on the most sensitive aquatic organism) should be weighted equally with carcinogenicity and other forms of human toxicity particularly in the case of metals, like nickel, where only a very small percentage of non-product outputs are in soluble form. (D56:2)

- The aggregation and scoring approach used in the tool requires close inspection and critical review by risk assessment experts. Single measures for human toxicity and ecological toxicity are wholly inadequate to represent the range of toxicological elements needed to characterize the hazard of a given chemical under a reasonable range of use scenarios. The single measure inappropriately aggregates very dissimilar and diverse endpoints, mechanisms of action, organisms (for ecological scores), dose-responses, test protocols, and conditions. Indeed, the scoring system displayed in Exhibit 1-2 is in basic conflict with guidance for effects assessment and dose-response evaluation given EPA's Draft Guidelines for Ecological Risk Assessment. (D30:7)

- One suggestion was that WMPT should use only human health risk in generating the overall chemical score. However, one person noted that human health toxicity data may not be better developed than ecological data. (S1s:27)

- It is not clear if human and ecological risk potential should be weighted equally because (1) the equal weighting results in double counting of persistence factors; (2) human health risk should be given a greater priority than ecological risk; and (3) ecological toxicity data is not as robust, nor as available, as human health data. (S1i:9)

- It is important that the screening tool include both human health and ecological risk considerations. (D55:cover2)

e. Adding vs. Multiplying P, B, T, and Mass

- The overall score should be the sum of the log PBT score and the absolute log score for the mass. Presently, if there is a mass that is less than one pound per year, then the log of the mass is a negative number. The mass score should always be a positive number. (P1:40)

- The threat from a chemical is proportional to the product of exposure and toxicity, while this scoring system treats them as additive, resulting in possible distortions. For example, chemical A has a mid-range exposure score and a mid-range toxicity score. Its threat to human health and the environment is moderate, and its score is 6 for human and 6 for ecological. Chemical B is a chemical like water, with a very high exposure potential, but it is virtually non-toxic. Its threat to human health and the environment is minimal, but its score is 7 for human and 7 for ecological. Chemical C is very toxic, but has virtually no exposure potential. Its threat to human health and the environment is also minimal, but its score is 5 for human and 5 for ecological. (P1:A-5)

- One participant mentioned that mass should be multiplied rather than added into the scoring algorithm. (T6:1)

- A simple integer between 1 and 3 does not represent the considerable breadth of hazard that might be posed by a particular chemical. To multiply a subjective integer index by a direct quantitative measure (quantity of chemical present in waste) does not give useful results, as generation quantity becomes the single, overriding factor in this analysis. For example, a compound generated at the rate of 10,000 pounds per year, which is extremely hazardous and fairly persistent, would result in a final risk index of (3 + 2 + 1) x 10,000 = 60,000. A compound generated at 100,000 pounds per year with only slight toxicity and not at all persistent would be given a final risk index of (1 + 1 + 1) x 100,000 = 300,000. (D70:2)

- If EPA determines that these chemicals need to be included in the WMPT, the Agency should ensure that it does so in a way that clearly indicates that they are a low priority for waste minimization activities. One approach would

be to divide the draft PCL into tiers, with the first tier representing chemicals of high concern, the middle tier representing chemicals of moderate concern, and the third representing chemicals of low concern. Alternatively, EPA could create a "zero" score for chemicals that have low toxicity, low persistence or low bioaccumulation. Thus, a chemical could receive a score of zero for any individual element, which would demonstrate that it has low toxicity, or is nonpersistent or nonbioaccumulative. Similarly, a chemical could receive an overall score of zero, demonstrating that it is non-PBT. By utilizing either one of these approaches, EPA could ensure that non-PBT, low ranked chemicals such as oxo process chemicals are not perceived as "guilty by association" simply as a result of their inclusion on the PCL. (D25:19-20)

- Each subcategory for toxicity should be multiplied together, each subcategory for exposure should be multiplied together, and then the toxicity and exposure total category scores should be multiplied together to yield an overall risk score. This approach would provide a more accurate assessment of risk. For example, currently a chemical with a persistence/toxicity/bioaccumulation score of 1/2/3 would have the same scoring as a chemical with a score of 2/2/2, in spite of the intuitive conclusion that a chemical which exists only for hours (i.e., a persistence score of 1) cannot bioaccumulate. This approach would broaden the scoring range for these chemical characteristics. In particular, the range of possible values for the exposure potential of a chemical substance would be broadened considerably from 2 to 6 under the current model to 1 to 9 under the proposed model. This approach would also lessen the impact of a low score. (D49:3,19)

- The threat from a chemical is proportional to the product of exposure and toxicity, not the sum. Addition of exposure and toxicity can result in distortions such as water, a high-exposure but virtually non-toxic chemical, receiving an overall score of 14 (7 for human hazard plus 7 for ecological hazard). (D8:2)

- The effect of addition in the WMPT scoring algorithm gives overall high rank to certain chemicals even if the amounts generated (i.e., mass) are extremely low. This applies to any of the factors. Multiplying would allow the scores to drop out if any of the factors were low. The equation should be changed to [(PxBxT)human+(PxBxT)environment]x mass. (S1i:8)

- The threat from a chemical is proportional to the product of the exposure and toxicity, while WMPT treats them as additive. This can result in distortions. (D55:3)

f. Other

- The technical basis for the waste minimization prioritization tool is severely flawed and in need of substantial review and revision. At best, the relative risk ranking methodology is a rough hazard screening tool. The WMPT does not use sound science or accurate risk assessment strategies, and neither the WMPT nor the PCL take actual exposure into account. The WMPT interprets risk values in the absence of uncertainties and assumptions that should be included in a risk calculation. Thus, the WMPT and PCL are not risk assessments, but instead are rough screening tools that should only be used if actual data are lacking. (D40:6-7)

- The waste minimization prioritization approach used by WMPT is a hazard-based chemical management device in that it focuses on inherent properties of chemical (i.e., toxicity, persistence, bioaccumulation potential) without factoring in considerations of concentration, duration, frequency, or probability of exposure. Hazard-based management should not in used in place of risk assessment when protecting human life and ecological systems. (D30:3)

- Noticeably absent in the description of the WMPT and the PCL rankings is any consideration of exposure as a function of calculating the risks associated with the listed chemicals. (D39:1; D41:1)

- PPG Industries strongly supports the concept of a voluntary, flexible waste minimization program, and we congratulate EPA for initiating the development of a risk-based tool to prioritize waste minimization efforts. While we believe the beta version of the WMPT currently focuses too heavily on evaluating hazard (inherent dangerous quality), to the exclusion of considering site-specific risk (probability of harmful outcome), we feel additional factors could be incorporated into the tool relatively simply, significantly enhancing the utility of this software. (D64:1)

- The tool is fine as a starting point to look at one waste stream vs. another and its purpose is best suited to relative ranking the hazard potential of one waste stream vs. another. It is not an exposure related risk assessment or even a risk screening (the exposure metric is way too crude). (D77:attachment)

- I am personally involved in the engineering side of environmental issues so I do not have the expertise to evaluate the model's scoring accuracy, but I suspect that the same pitfalls that plague risk assessments will also plague this model. (D73:1)

- The WMPT assumes that hazard is equivalent to risk. The data elements included in the WMPT are factors that represent hazard characteristics inherent to the various chemicals. Hazard, by definition, is the potential to cause adverse effects. Hazard is independent of the conditions of use of the chemical, and is a static factor. In contrast, exposure is the potential for contact between a hazard and the environment. The conditions of chemical handling are prime determining factors in measuring exposure. In order to be a risk-based prioritization tool, the WMPT must consider the potential exposure of humans or the environment to the chemical in question. It is important to keep in mind that risk is a function of both exposure and hazard. We note several instances of inconsistent usage of the terms "hazard" (or "toxicity") and "risk" in the tool and the manual, and caution EPA to fully understand the wide reaching effects of choosing one term over another in each context in which these terms are used. (D76:1,2)

- Each category is considered equal in importance to every other category. We believe this is a major error, as surely the importance of a human health effect should outweigh the score assigned due to the reportable quantity that has been assigned to the chemical. Weighing all categories equally leads to some wildly incorrect analyses. (D76:5)

- While BHP Copper appreciates the complex range of goals the EPA faced in creating the WMPT, as well as EPA's mandate to create a relatively simple and flexible tool for assisting stakeholders to clarify their waste reduction priorities, the Company believes that simplicity was gained at the expense of accuracy and practicality. The WMPT User's Guide points out that the tool prioritizes chemicals-based on an "inherent hazard" which is defined by EPA to encompass persistence, bioaccumulation potential, toxicity, and quantity. BHP Copper believes this definition to be incomplete and to provide inadequate parameters which cannot be applied judiciously to the 4700 different chemicals analyzed in the software program. Specifically, BHP Copper believes that any tool which attempts to rank chemicals by their potential hazard to human, plant and animal health should include a measure of the potential exposure to that substance. Potential exposure is determined by evaluating a substances bioavailability, which in turn is linked to speciation of the particular substance. A further confounding factor is the environmental medium in which a substance is present. The failure to take into account these critical factors when assessing a substance's risk potential throws into question the validity of the prioritization effort. (D61:2)

- In order for the WMPT to be truly effective in targeting specific chemical wastes for minimization programs, it is critical that realistic considerations be given to the risks involved rather than relying on the surrogate indicators of persistence and bioaccumulation. The basis for determining waste minimization needs and evaluating performance should be risk-based and should consider other factors such as legislative requirements, technology feasibility, and social and economic impacts. The American Crop Protection Association believes that the WMPT must be modified to give a more accurate ranking of chemicals according to their potential risks in waste environments.

The important factors to consider in listing chemicals were accurately reflected by Dr. Lynn Goldman, EPA Assistant Administrator for Prevention, Pesticides and Toxic Substances, in her statement before the House Committee on Government Operations Subcommittee on Legislation and National Security (February 1, 1994) and in the National Academy of Science/National Research Council as provided in its 1983 report entitled "Risk Assessment in the Federal Government: Managing the Process" and reiterated in its recent report "Science and Judgement in Risk Assessment" (1994 NAS/NRC report). (D69:2,3)

- There are serious flaws with the prioritization of chemicals of dissimilar class (e.g., benzene is scored lower than zinc; barium is ranked equal to cadmium and above arsenic and lead; silver is ranked equal to lead and above benzene, malathion, and mustard gas) which are due to assigning risk rankings based on only three criteria and using data and information ill-suited for the purpose of ranking human health risks. EPA should examine the basis for scoring these compounds and what caused these illogical results. (D32:7,8)

- The PBT characteristics are important factors in calculating risk, but, by themselves, are not determinative of risk. (D27:17)

- Identification of a chemical as a PBT is the first step of risk characterization. A waste minimization program will also incorporate information on available waste management practices, actual potential for human exposure, and costs and availability of less toxic substitutes. (D27:17)

- The WMPT does not consider factors bearing on risk other than hazard. (D27:18)

- Major waste minimization decisions should be based on scientifically valid risk assessment and on site-specific data. (D41:1)

- The WMPT was developed to identify and score chemicals based on their persistence, bioaccumulation and toxicity for use in establishing waste minimization priorities. However, the WMPT in its current format fails to accomplish this objective. (D35:1)

- The WMPT as designed will not provide an assessment of risk, but more so a relative comparison of hazard. The persistence and bioaccumulation components in the WMPT do not adequately address a chemical's exposure, which, along with a chemical's hazard evaluation, is necessary to characterize risk. (D35:2; D37:i)

- In order to develop a science and risk-based tool a number of items need to be considered including exposure, chemical properties and behavior in the environment. Due to the diversity of chemicals, chemical forms, toxicity, modes of action, degradation, and waste management strategies, developing a tool that adequately covers all these aspects is complex and has not been achieved in the WMPT. (D36:ii; D36:1)

- Most risk management decisions are not clear cut and involve weighing alternatives which may reduce the risk on one consequence but increase the impact of another. These variables are not addressed in a simple model such as the WMPT. (D37:ii)

- Any tool designed to identify waste reduction opportunities must be based on the relative risks—not the relative hazards—associated with each chemical. (D49:6)

- EPA should clearly identify what the tool is and is not (i.e., it is a simple screening tool and is not a risk assessment tool). WMPT should not be considered a substitute for risk assessment in policy and decision making. EPA should ensure that WMPT maintains consistency with current and future human health and ecological risk assessment guidance (e.g., chemical mixtures and proposed ecological risk assessment guidance) (D55:cover2)

- It is possible that misperception of the tool's intended use might result in the regulated community believing that this tool can be used in place of a formal risk assessment. (D55:1)
- Communicate to the public that the WMPT is a risk screening tool not a risk assessment tool. Clearly state how the WMPT should and shouldn't be used. (S1i:13)

- Provide a clear explanation of what the resulting ranking (i.e., overall chemical scores and relative ranks) represents. (S1e:15)

- Test the WMPT overall chemical scores (ranks) against a risk assessment ranking tool to compare and validate the WMPT resulting lists. (S1e:15)

- In some state agencies, many risk assessment-type tools have been presented that do not carry out the full risk assessment. This seems to be confusing managers who (in using the tools' outputs) have trouble distinguishing between the capabilities of such tools and risk assessments. (S1s:24,25)

- The user's guide states that WMPT is a risk-based screening system or a simplification of the risk paradigm (i.e., it takes into account both toxicity and exposure when determining relative risk). Even given that it is a simple screening tool not designed to perform complete, site-specific quantitative risk assessments, the system actually ends up ranking chemicals on the basis of hazard more than risk. This is because WMPT uses persistence and bioaccumulation to estimate human and ecological exposure potential. However, persistence and bioaccumulation are inherent characteristics of chemicals and do not predict whether humans or wildlife will be exposed to them. (D31:9)

- According to EPA, WMPT is intended "to provide a screening-level assessment of potential chronic (i.e., long-term) risks to human health and the environment" (Waste Minimization Prioritization Tool, User's Guide and System Documentation, p. ii). Unfortunately, however, WMPT does not provide any guidance as to a listed chemical's true environmental risk relative to other chemicals. As a result, WMPT will not achieve EPA's intended results. This failure is largely due to the fact that WMPT is based on erroneous scientific assumptions and gross oversimplifications that do not reflect real-life considerations. (D54:2)

- The WMPT fails to consider key factors bearing on risk. (D27:ii)

- The existence of a chemical in the environment does not in and of itself imply adverse effects in human or ecological populations. The presence of any chemical at any concentration does not equate to risk or even impact in the absence of a receptor population and completed mechanisms of transport and exposure. (D40:7)

- The current basis for the ranking scale should be abandoned or fundamentally revised. The prioritization assigns a relative ranking merely as a consequence of a chemical's existence. Presumably, EPA adopted this method because it believes "any chemical may be harmful under certain conditions." (D40:7-8)

- The arbitrary and flawed nature of the methodology is exemplified when one considers the relative rankings for the chemicals. For example, the science behind ranking ethanol with a higher value than carbon disulfide and methanol is questionable. Additionally, under the scoring procedure, the user is unable to distinguish those chemicals which were ranked due to the mere existence of data from those chemicals for which the data actually demonstrate that the properties of low-level toxicity, persistence, and bioaccumulation are present. This methodology is flawed and must be abandoned, or at a minimum, be revised. (D40:8)

2. Focus on PBT and Mass as Screening Criteria

a. Consideration of Management and Release Potential

- WMPT should be applied to the chemicals and volumes actually released to the environment. If waste is reused, recycled, or treated biologically, by combustion, or by other means, the risk can be vastly reduced. Elimination of waste with high as-generated risk but low as-managed risk is not nearly as valuable as elimination of waste with moderately high as-generated and as-managed risks. (D32:7)

- Ciba does not manufacture 2,4,4'-trichloro-2'-hydroxydiphenyl ether (triclosan) in the United States. Ciba currently imports 2,4,4'-trichloro-2'-hydroxydiphenyl ether from England for use in applications which are strictly regulated by FDA under the Food, Drug, and Cosmetic Act (FDCA), and by EPA under the Federal, Insecticide, Fungicide, and Rodenticide Act (FIFRA). Although "grand fathered" on the Toxic Substances Control Act (TSCA) Chemical Inventory, there are currently no "industrial" uses for triclosan. Warehouse and distribution centers are limited to two facilities in the United States, neither of which processes the material. As a result, releases of triclosan to the environment associated with Ciba's importation, warehousing and distribution are negligible or non-existent. (D13:2)

- Triclosan is utilized as an active ingredient in first-aid products, antigingivitis/anti-plaque dentrifices, surgical scrubs and professional hand care products regulated by the FDA based on its efficacy as an antimicrobial agent and is also used at low concentrations in consumer products and cosmetics such as underarm deodorants, and liquid and bar soaps. The antimicrobial effects associated with FIFRA-regulated products containing triclosan also provide significant human health benefits. (D13:2)

- Route of release is not considered despite its effects on persistence and exposure potential. (D27:18)

- The WMPT is simply too unsophisticated to adequately identify, in and of itself, waste streams for reduction. Rather, a number of additional factors should be taken into consideration, as discussed later in this document, before a facility can determine which of its waste streams are the best candidates for risk minimization. Because facilities take a number of other factors into consideration, there is no guarantee that any list of priority constituents developed by the Agency using the simplistic WMPT and against which national goals will be measured will correlate to those constituents in waste streams prioritized for reduction by individual facilities across the nation. Thus, there is no guarantee that the national goals set by EPA will be achieved. (D75:3)

- Eastman strongly supports voluntary, flexible waste minimization programs that allow individual facilities to consider site specific factors. Waste minimization teams are in place throughout Eastman, to identify potential projects at the process/division level. Such projects must then compete for available funds on a corporate, annual basis. The consideration of certain elements is instrumental in prioritizing the projects for funding, including consideration of the following; human health impacts; environmental impacts; costs; efficiencies of the generating process; performance of potential substitutes; effects on regulatory compliance; customer specifications for products; liability potential; and incremental benefit to human health and/or the environment. (D75:4)

- The WMPT does not include cost/benefit analysis in the establishment of waste minimization priorities. Reilly agrees that the establishment of priorities for waste minimization is important to focus resources and efforts in an orderly and efficient fashion. By not including in the WMPT any mechanism for the conduct of cost/benefit analysis, EPA appears to assume that industry has unlimited resources to devote to waste minimization. Unfortunately, this is not the case. To remain economically competitive, companies must concentrate waste minimization efforts where they will see the "biggest bang for the buck." It is unrealistic to believe that industry should pour vast amounts of resources into an effort that will not reduce as much potential exposure as will a project that may not have scored as highly using the WMPT. Factors that are entirely neglected in this tool are the consideration of availability and feasibility of various waste management practices, the actual potential for exposure to humans or to the environment (regardless of mass), time for completion of the waste minimization

project, and the availability and cost of less hazardous substitutes for the chemical in question. To be effective, the WMPT must take into consideration the economic law of diminishing returns, and apply sound economic logic to the prioritization process. Without a sound economic basis, this tool does not encourage industry to make decisions with the best interest of the American economy in mind. (D76:3)

- The as-generated approach is inconsistent, from a policy perspective, with the approach being taken by the RCRA hazardous waste listing program. The listing program is moving towards a contingent management approach—both in individual listing decisions and in the broader effort being undertaken through the Hazardous Waste Identification Rule. (D75:12)

- In the end, the WMPT and PCL will confuse citizens by focusing their attention on whether or not a product or waste contains, or could contain, a listed chemical, regardless of whether the product or waste is managed properly or poses a risk. (D48:12)

- The stigmatization of the use of chemicals listed by EPA runs counter to the waste minimization policies of federal law. Congress enacted RCRA in 1976 with the intent of ensuring that hazardous wastes were managed and disposed of safely. The 1976 law focuses on the proper management of wastes rather than forced source reduction or stigmatization of chemicals. This management-based policy was reflected in the first major body of RCRA regulations which EPA issued on May 19, 1980 (45 Fed. Reg. 33,073). When Congress amended RCRA through enactment of the Hazardous and Solid Waste Amendments of 1984, it retained the management-based policy reflected in the 1976 law. (D48:7)

- An aspect of the tool we liked is a "Hazard as Generated Approach" that pushes people toward pollution prevention rather than a "Hazard as Managed" approach that involves many uncertain assumptions. (D77:1)

- EPA chose "hazard as generated" over "risk as managed." Multiple reasons were given, including the preference for source reduction and recycling, the time and resource-intensive process required for estimating risk, and the importance of PBT characteristics for chemical risk screening. Eastman has consistently commented to the Agency that this approach is inappropriate. If a given facility is to allocate limited resources to achieve the greatest reduction in risk, it must consider how a waste stream is managed and the potential for exposure associated with that management method. To its credit, the User's Guide does point out that the WMPT is a simple chemical screening approach and can "potentially be used along with supplemental management and exposure information to more closely approximate site-specific risk concerns" (pp. 1-6 and 1-7, User's Guide). (D75:2)

- The Agency's tool focuses prioritization activities on "source reduction," whereas Eastman focuses its prioritization activities on the full pollution prevention (waste minimization) hierarchy—source reduction, reuse/recycle, treatment and as a last resort, disposal with a preference for source reduction. The WMPT, in Eastman opinion will be minimally useful to most companies, because of its limited focus on waste streams with PBTs as generated and its inability to incorporate other factors of importance on a site-specific basis. It can only serve as a rough screen to help identify onsite waste streams containing PBTs. While beneficial in serving that purpose (assuming adequate "fixes" are made to the current tool), there are many other wastes, many other constituents, and many other factors that must also be screened/considered by a facility prior to committing resources to reduction projects. (D75:6-7)

- The "RCRA Enforcement Targeting System under the RCRA Enforcement Division is developing a scoring system for inspection targeting. The system can be used to (1) rank constituents/chemicals for allocation of enforcement resources for RCRA areas of concern; (2) build a chemical inventory that links chemicals to waste codes; (3) nationally rank chemicals/waste codes by region; (4) track progress for the purposes of the GPRA; and (5) track chemicals by waste codes and waste streams." The screening tool developed for the OSW to establish

source reduction and recycling priorities as part of the Waste Minimization National Plan will be used as a model for this scoring system. EPA plans to target waste streams containing PBTs for purposes of waste minimization and enforcement, regardless of how such waste streams/constituents are managed and regardless of the level of risk such waste streams/constituents pose to human health and the environment as managed. This is inappropriate, will result in the misallocation of resources by the Agency, and may minimize rather than maximize human health and environmental benefits. If facilities focus on minimizing waste streams strictly on the basis of PBT content, the reduction of risks may be insignificant, and facilities may focus on the wrong waste streams in terms of risk reduction. (D75:9-10)

- The tool does not account for the way waste is managed (how risk is mitigated). While PPG Industries strongly supports a strategy of source reduction where possible and economically feasible, as a practical matter, there is a continuum of management techniques—recycling, reclamation, substitution, use and reuse of secondary materials as feedstock, energy recovery, treatment, responsible management of residues, and control of releases. All have a role to play in controlling total risk. Inclusion of a management method factor would significantly enhance the practical utility of the tool. The management choices made on a continuing basis are a vital part of a total program, and something to which we are held accountable by the communities in which we do business. The inability to eliminate or reduce a particular waste stream does not absolve us from the obligation to continuously reduce the overall risk of our operations. As an illustration, we may not have the technological ability today to eliminate coincidental production of an undesired component. The best we may be able to do is lower the overall ranking for the waste stream by treating the residues so they no longer pose the same hazard. That is not a failure of the waste minimization program, it just means that attention and resources need to be moved to the next problem that can be addressed. When the first issue again rises to the top of the priority list, it will be reevaluated, and the process begun anew. Waste minimization is and must remain an inherently iterative process. (D64:6)

- The PCL which results from application of the Agency's screening model is unrelated to risk. EPA's list provides no information about how or why the chemicals are produced, used or managed within each facility. Exposure, a critical element of risk assessment, is not addressed. (D48:11)

- The WMPT is, at best, a rough screen for considering which waste streams to prioritize for minimization. Facilities consider a multitude of factors, including the efficiencies of a process, risk issues, cost, performance of potential substitute chemicals, and effect on customer specifications, and there may not be a close correlation between the constituents in wasters targeted by the national program and those targeted by individual facilities and in aggregate by industry. A topdown program (EPA decides which constituents/waste streams should be minimized), instead of a bottom-up program based on information from individual facilities and aggregated at the State and then national level (actual data on which constituents/waste streams are being targeted for minimization), may result in a failure to meet national goals. (D75:11)

- The purpose of the Waste Minimization National Plan is stated as providing a 50 percent reduction in the presence of the most persistent, bioaccumulative and toxic (PBT) chemicals in hazardous waste by 2005. Properly managed wastes under current RCRA regulations pose little or no risk to human health and the environment. Therefore reducing RCRA waste volume by 50 percent will have little or no effect on human health and the environment. (D34:1)

- Pesticides are subject to regulation under a number of statutory schemes, other than FIFRA, pursuant to which a waste minimization program is a required element. (D38:2)

- There is only one manufacturing plant producing pendimethalin in the U.S. Because manufacturers already strive to minimize their product going into waste streams instead of the market, pesticide active ingredients have a relatively low concentration in waste. (D36:4)

- Ethylene glycol ethers and propylene glycol ethers are rarely found in hazardous waste, and should not be included among any list or ranking of PBT chemicals. (D45:2; D46:1)

- The overall chemical score generated by WMPT incorporates quantity (mass) but does not incorporate the likelihood of a chemical release. Therefore, the focus is on wastes as-generated rather than on wastes as-managed. EPA should investigate incorporating information about a chemical's likelihood of release within the additional criteria used to score chemicals. (E1:10)

- Waste releases of triclosan at drug and pesticide manufacturing facilities are not prevalent for the following reasons: (1) Approximately 90 to 95 percent of all the triclosan imported into the United States is used in applications governed by the FDA under the FDCA. In all cases, FDA current good manufacturing practices (cGMPs) are practiced at these sites, thus controlling the use of triclosan during all aspects of the product's life cycle; (2) The remaining 5 to 10 percent of all triclosan imported into the US is consumed in the development of antimicrobial pesticides which are regulated by EPA under FIFRA. Because of its antimicrobial pesticide classification, the use and disposal of triclosan must be strictly controlled; (3) triclosan's cost makes it prohibitively expensive to use in a manner that will result in frivolous waste or releases; (4) Under its Responsible Care and Product Stewardship Program, all uses of triclosan are qualified prior to sale in order to ensure that the product will be used in accordance with all applicable laws and regulations. Furthermore, its Material Safety Data Sheet suggests that all triclosan waste be disposed of in accordance with all Federal, State, and local laws and regulations. (D13:2)

b. Other

- Two participants stated that WMPT should include environmental health and safety considerations, such as the flashpoint for acetone and isopropyl alcohol, in addition to P, B, and T. Health and safety considerations also play a role in determining potential risks and are important components of decision making processes at industrial facilities. (T6:2)

- An effective waste management methodology must allow stakeholders to balance risk with other factors like exposure potential, cost, time, product quality, and process integrity. (D27:10)

- The tool will be more valuable to users if it can screen more chemicals rather than less. (D55:cover3)

- The WMPT may result in projects that fail to contribute significantly to a reduction in risk, because too few criteria are factored into the analysis, and because significant flaws within the tool (as damaged later) have not been corrected. (D75:5)

- The tool should only be used to help individual facilities begin their evaluations of which wastes to consider for reduction. To accomplish this the tool needs revision to be flexible enough to incorporate professional judgment, site-specific parameters, and additional data. (D36:i; D36:1)

- Route of exposure, which is equally important as hazard in determining risk, is not adequately addressed by the WMPT. It is difficult to evaluate this tool and the underlying data without addressing the issues of exposure routes and durations, since chemicals pose different hazards depending on both. Obviously, any approach must be relatively simple to be useful as a screening tool; the most direct method to account for these concerns might to be to add a new field supplied by the user, identifying the exposure scenario(s) of greatest concern at the specific facility in question. These "switches" would then be used to filter or weight the underlying toxicity data. As an example, for an organic wastewater being managed under RCRA incineration rules, chronic inhalation exposure by the public might be the most important route to consider; for the same waste being managed by secondary

biological treatment, oral ingestion routes would be more important. This is a critical issue, as resources should be applied preferentially to existing, high risk situations, of which exposure is one determining factor. (D64:6)

- PPG Industries' ranking system includes several other factors that we feel are important considerations in prioritizing waste minimization efforts. Our toxicity component includes consideration of *physical hazards*, in addition to acute and chronic health hazards—similar to the logic used for classifying chemicals as hazardous under SARA 312. This is also an important area of concern under RCRA. Issues of employee and public safety are often, and sometimes inversely, linked to environmental actions, and we strongly feel this relationship needs to be accounted for in the decision making process. We also consider mobility in the environment, based on the physical form of the specific waste stream being managed. We define the volume factor as log(tons)+1, based on the annual volume of the whole waste stream (rounded up to the nearest whole ton); using this approach shifts the ranking scale away from a zero value and keeps the volume factor roughly on a par with other factors. Finally, we try to consider the cost of our current management method, as well as new opportunities for economic recovery (such as increased production capacity). The prioritization schemes developed by other companies will include these and others in many possible combinations. EPA could play a vital leadership role in promoting waste minimization among businesses and institutions of all sizes by expanding the tool to allow inclusion of factors like these, to be specified by the user facility, as their needs dictate. (D64:6,7)

- Chemical mobility within a media should be included in the model, including information on partitioning from one media to another, to help State programs identify and evaluate potential cross-media transfer issues. (D55:5)

- Persistence and bioaccumulative ability are not risks in-and-of themselves. They merely serve to increase toxicity and other hazards. That is, if two materials pose similar toxicity, the one that is more persistent will, therefore, remain toxic for a longer period of time (i.e., Risk = [Toxicity x f(Persistence: Bioaccumulation)] x Quantity). To illustrate this point, based on the current model, a compound which is highly stable and highly bioaccumulative, but which poses absolutely NO toxicity, would generate a hazard index of 1 + 3 + 3 = 7. A compound such as hydrogen chloride, which is not persistent or bioaccumulative but has an extremely high toxicity, would yield a hazard index of 3 + 1 + 1 = 5. This is certainly not a result that such a model should produce. (D70:1)

- The issue of a component-based, versus a waste-based, approach is a difficult one. The only reasonable stand is a hybrid approach. Fundamentally, RCRA is a process-based, waste-based program. Because of RCRA's broad reach to include "derived from" and "contained in" materials, there is little or no incentive to reduce any single component of a RCRA regulated stream—the waste is still RCRA regulated, with the same paperwork, the same labor, and the same cost. The component-based approach merely adds a new layer of recordkeeping on top of the existing requirements. While there remains the extraordinary step of attempting to delist a RCRA waste, substitution of a toxic component for a less toxic one in most industrial cases would not lead to a stream which could exit RCRA. On the other side, however, there is clearly a need to deal with the issue of component concentration. Of the 279 million tons of RCRA wastes reported in the 1995 biennial report, 267 million tons (96%) was wastewater. How should we compare the relative risks of large volume, low concentration streams versus small volume, highly concentrated wastes and still keep it simple enough to be of utility? First, it is important to distinguish between remediation wastes and ongoing waste generation associated with production. Remediation materials, which include large quantities of low level wastewater, debris, and media are obviously not the desired targets of waste minimization. The only "list" the tool should generate is a list of RCRA wastes for a particular facility, with an overall composite score for *each waste stream*; different waste streams may have the same RCRA code. This RCRA waste score should be based on the whole stream, not just a portion of the components in the waste. A simple weighting mechanism to generate "average" PBT scores, based on composition information supplied by the user, might be best. Taking a conservative approach (i.e., scoring the mixture at least as high as the most "toxic" component) tends to skew scores to the high end of the scale, lessening, not enhancing, differentiation between waste streams. To accomplish this, the data set would need to be completed, in some fashion, for every component in a RCRA waste. For example, "inerts" carrying the contaminants (i.e., water, air,

soil) would have to be rated too, probably at the "bottom" of the scoring range to keep the final scores on the original scale. With this kind of an approach, the results of the prioritization would be based on actual process streams, which in turn relate directly to business activities and waste minimization projects that can improve efficiency and cut waste. We see no practical advantages to compounding quantities of a specific component across different waste sources, as there will be no common solution to waste streams with different origins. (D64:5,6)

- The evaluation process should be step-wise, as described above, to conserve resources and to focus on the MOST persistent, bioaccumulative, and toxic constituents of hazardous wastes, as called for in the 1994 Waste Minimization National Plan. The DRAFT Prioritized Chemical List (PCL), supplied as an output of the WMPT, lists chemicals by total score, instead of by persistence and/or bioaccumulation first. We believe it would be much more focused and relevant to list chemicals by high priority bioaccumulation potential and persistence first, i.e. only those chemicals with a score of 3 for both persistence and bioaccumulation (and for both human & ecological health, e.g. total score of 3+3+3+3=12) would be considered further. Toxicity would then be used to rank this group of chemicals from 18 down to 12 in prioritized order for waste minimization. Thus a whole group of low risk chemicals could easily be eliminated from consideration early in the process (e.g. sodium chloride, ethylene glycol, anything with a score of 11 or less for persistence plus bioaccumulation scores). This would ensure a focus on the true, potentially, PBT substances. Note that the consideration of persistence and bioaccumulation potential, then toxicity, is consistent with the "PBT Policy Implementation Guidance" (Chemical Manufacturers Association 1996) that EPA cites as an example of previous efforts to prioritize actions on PBT substances. (D59:2)

- However, given our recommendations on developing a sequential methodology for the WMPT, it is clear that sodium dichloroisocyanurate would not make the first bioaccumulation/persistence "cut". We strongly recommend that EPA adopt such a sequential methodology to focus on the MOST important PBT compounds for waste minimization. (D59:6)

- The most significant problems in the application of the WMPT to pentachlorophenol is the failure to consider factors such as pH and temperature that profoundly influence a chemical's environmental behavior. (D48:13; D48:19-20)

- The only measure of exposure the WMPT includes is the "mass" category. Persistence and bioaccumulation factors are data that are inherent to the individual chemicals themselves. We do not agree that they are measures of exposure, but rather, of hazard. Once the test data has been developed, the persistence factor and bioaccumulation factor remain the same, independent of the chemical's potential for release to the environment. Therefore, we maintain that persistence and bioaccumulation are wrongly labeled as "exposure factors." (D76:2)

- Reilly believes that it is equally as important to consider the physical and chemical properties of a chemical when evaluating the potential for it to enter the environment and be a source of chemical exposure. Equally as important is the chemical's mobility once in the environment. For example, it stands to reason that gases, upon release into the environment, will diffuse further than liquids, which will likewise spread further than solids. Likewise, there are comparative measures among the various physical states. For example, to compare the exposure potential to the various liquids, one must compare the vapor densities and the vapor pressures of the liquids to each other. Therefore, a significant flaw exists in the WMPT by the failure to include physical and chemical data in the exposure evaluation. (D76:2,3)

- The WMPT should focus on the chemical constituents most likely to exhibit the characteristics of persistence (P), bioaccumulation (B) and toxicity M, or PBT properties. If a chemical is not persistent in the environment, then the analysis does not need to go further, since persistence is a necessary condition for bioaccumulation. If the chemical is persistent, but not bioaccumulative, the screening can normally stop at that point, since the chemical is unlikely to reach a concentration that is hazardous to human or ecosystem health. If a chemical is both persistent

and bioaccumulative, then toxicity should be examined to determine whether the potential concentrations could rise to a level, through bioaccumulation, that would be of concern for expression of toxic effects in exposed individuals or aquatic biota. Only if a chemical exhibits all three characteristics would it be classified as a highly PBT substance and thus rate the priority for reductions identified under the Waste Minimization National Plan. (D59:1)

- The tool should continue to use the hazard as-generated approach to identify priorities because this approach promotes pollution prevention as a solution. (D55:2)

- EPA should remove the mass component from the WMPT or at least not apply it to low ranking compounds. Use of the mass component could produce the environmentally detrimental result of focusing waste minimization efforts on low toxicity, non-bioaccumulative, non-persistent chemicals simply because they are used in large quantities. (D25: ii)

3. Persistence Scoring

a. Data Quality Hierarchy

- A weight-of-evidence approach is needed for biodegradation assessment, however, a revised approach should be developed which relies on measured data whenever available, rather than on model predictions. In the absence of data, the non-linear model should be used since this model has incorporated more actual data than the Ultimate Survey Model and has been subjected to recent validation studies (Rorije et al., 1997). The non-linear model can be best used to indicate those chemicals that will probably biodegrade slowly or not at all in a ready biodegradation test. Given the potential to falsely classify a biodegradable chemical as non-biodegradable, recommended fencelines should be carefully designed to take this bias into account. (D29A:16)

- Measured data should be used instead of predicted data whenever possible. If it is necessary to use predicted data, the Ultimate Survey Model and the non-linear probability models are the best models to use. The Ultimate Survey Model looks at the breakdown to CO2 and water, while the non-linear probability model looks only at first state biodegradation. (S1i:12)

b. Use of Measured vs. Predicted Data; Data Sources and Accuracy

- Persistence scores in the WMPT are based only on hydrolysis and biodegradation potential. While these processes should be considered, other abiotic degradation mechanisms may be critical in determining the environmental persistence of hydrocarbons. For example, photolysis serves as the primary degradation route in surface waters for many of the 3 to 5 ring PAHS (Neff 1979; Howard et al. 1991). As a result, half-lives in surface water for these compounds are one of more orders of magnitude lower than predicted based on biodegradation considerations alone. (D29A: 15)

- As with 4,4'-MDI, however, the WMPT did not take into account the well-documented environmental chemistry and behavior of the isocyanate group in evaluating the potential persistence of TDI and the 2,6- and 2,4-TDI isomers. The hydrolysis estimation used in the WMPT was the HYDRO Program, Version 1.0. This program did not include the isocyanate group as a hydrolyzable functional group in organic chemicals. The later version of this program, HYDROWN Version 1.6, corrects this error and reports that, for isocyanates, "even at low pH, the hydrolysis rate is very fast: t½<10 minutes." Meylan and Howard (1986). (D19:10-11)

- TDI reacts rapidly with water to form predominantly inert polymeric polyurea products. Only a small amount of the hydrolysis product, toluenediamine (TDA), is formed. Yakabe et al (1991); Brochhagen and Grieveson (1984). In addition, the kinetics of phenyl isocyanate reactions with water have been studied extensively. See Castro et al. (1985), Morton and Deisz (1956). Phenyl isocyanate is very similar to TDI and has been studied because of its simpler, monofunctional reactions. The pseudo first order rate constant for the reaction of phenyl isocyanate with water at 25°C was $3.39 \times 10^{-2} s^{-1.}$ Castro et al. This reaction is base catalyzed but not acid catalyzed. Thus, in water solution at pH 7 or less, the half-life of phenyl isocyanate is calculated to be 20 seconds. At higher pH values, the half-life is calculated to be less than 20 seconds. In addition, Morton and Deisz tested phenyl isocyanate in water/dioxane solutions. Extrapolation of these results to environmental conditions suggests a half-life of a few minutes. This half-life, though longer, still indicates rapid reaction of aryl isocyanates in the environment. Laboratory studies also have been conducted which demonstrate that, with stirring, the reaction of TDI with water is rapid. Yakabe et al. (1989-1994) reported an apparent half-life for TDI of about 1 hour. The water reaction rate was faster in experiments with lower initial concentrations of TDI. Exhibit 2 (attached) shows the more rapid reaction with more vigorous stirring and a lower concentration of TDI. In this study, an apparent half-life of a few minutes was evident. Ode (1997). These data support a persistence score of 1 for TDI. (D19:10-11)

- The half-life for triclosan in humans is 4-6 hours. (D13:3)

- The third document is "Use and Exposure Profile for Isopropanol" prepared by OPPT in April, 1997 (Appendix V). This document also expressly recognizes that isopropanol does not persist in the environment. Specifically, the document notes the following: (I) "An overall removal of 98 percent is predicted [during secondary wastewater treatment] because significant biodegradation is expected;" (ii) "Isopropanol is expected to be readily biodegraded in aerobic and anaerobic environmental settings;" (iii) "isopropanol is not expected to sorb to soils or sediment;" and (iv) "the estimated volatilization half-life form a model river is 2.5 days. However, volatilization will be mitigated by the relatively rapid rate of biodegradation expected (half-life on the order of 1 day)." The OECD SIDS IAR also provides an atmospheric degradation (OH radical attack) half-life of 18 to 25 hours. (D16, 7-8, Appendix IV)

- For BTEX and 2 or 3 ring PAHs, the ultimate survey model (USM) yields a score in the 2 to 3 range (Table 7). Given these results and the proposed scoring fencelines, these compounds are assigned a moderate biodegradation potential (acenaphthylene is the exception and is deemed highly biodegradable, i.e., assigned a score of 1). However, this characterization is not consistent with measured data from standardized biodegradation tests. For example, ultimate biodegradation of benzene, o-xylene and p-xylene determined in EBSI laboratories using the OECD 310 F manometric respirometry 28 day test were 66, 70 and 88%, respectively. These chemicals would therefore meet the stringent "ready" biodegradation definition used in European Union classification system (i.e., > 60% in 28 days) but are characterized by WMPT as only moderately biodegradable. Numerous literature studies confirm the highly biodegradable nature of BTEX and lower molecular weight PAHs in soil and water (Urano and Kato, 1986; Tabak et al., 1992; Howard et al., 1991; Harris, 1996). This conclusion is further supported by the predictions obtained from the non-linear probability model included in the WMPT, which indicates a high biodegradation likelihood (c.f. Table 7). Curiously, the non-linear probability model predicts that acenaphthylene would have the lowest biodegradation probability fro this group of chemicals (i.e,. P=0.7) but, as mentioned above, this compound is correctly characterized as highly biodegradable in the WMPT scoring. This discussion clearly indicated that BTEX should be assigned a low persistence score based on high biodegradation potential. (D29, Appendix page 15-16)

- There are many chemical used throughout the modern economy which are valued specifically because of their benign persistence. By persisting in the environmental under adverse conditions, many chemicals, and especially color pigments, perform valuable functions. If these compounds were to breakdown quickly in the environment, the functions performed by those chemicals would require continuous replacement. Such continuous replacement would require high quantities of time, energy, production and pollutants. A common example of this would be the bright red traffic stop sign. Without safe, non-toxic compounds which persist in the environment, the stop sign either has to be continuously repainted or replaced. Such results are not efficient and certainly do not protect human health or the environment. Indeed, the results are simply wasteful. Similar results and examples would include vehicle coating, outdoor signs, printed materials, products made from plastic resin, and building materials. Under the current algorithm, color pigments would engender a score of a at least "10." Such results are completely out of proportion with the risk posed by color pigments. Organic color pigments are extremely stable in the environment, they are not shown to be acutely or chronically toxic and they have not caused or created toxic conditions in the environment. (D12:9)

- The WMPT addresses only the estimated biodegradation of the chemical and does not account for the possibility of abiotic chemical degradation through hydrolysis, photo-oxidation, photolysis, or reduction (processes that can be important for many organic chemicals). (D48:19-20)

- EPA should eliminate the default persistence score of 3 for metals. For all chemicals other than metals, EPA assessed environmental persistence by evaluating biodegradation and hydrolysis properties. EPA did not evaluate biodegradation and hydrolysis properties to predict or compute persistence scores for metals. Instead, EPA

classified metals into one of five categories. All the elemental metals EPA evaluated received a score of 3 (high persistence) for both human and ecological exposure. (D43:4-5,7)

- "Persistence," as that term is applied to organic chemicals, is not a suitable criterion to evaluate the potential hazard of metals. (D43:5-6)

- The high persistence scores for elemental metals may adversely and unfairly be used to characterize metal compounds. Because metal compounds are not scored for persistence, users may erroneously use the persistence value recorded for the elemental metal. The use of the persistence value for metals will cause significantly and unfairly inflated overall chemical scores for metal catalysts and similar compounds. (D43:6)

- Non biotic degradation pathways are not included in the Persistence score. EPA does not consider photolysis, oxidation, evaporation and polymerization in modeling the persistence in the environment. For naturally occurring molecules such as the Pulp Chemicals Association chemicals, there are natural pathways that prevent accumulation to toxic levels. For example, ß- Pinene is a light volatile oil, a major constituent of turpentine, that readily oxidizes in the atmosphere, will polymerize and has low water solubility. All of these factors should be considered along with biodegradation in evaluating environmental fate. The Pulp Chemicals Association believes that by using data such as the Biodegradation Ultimate Survey Score and ignoring other degradation pathways, EPA incorrectly assigns a score of "2" to ß- Pinene for Persistence and then compounds the error by using the Persistence factor twice. (D60:3)

- It is clear from the above discussion and data analysis that sodium dichloroisocyanurate is NOT persistent or bioaccumulative, therefore a rating value of 1 - low concern for four scoring elements is recommended (two each for bioaccumulation and two each for persistence). (D59:6)

- The traditional biodegradation related measure of "persistence" that is used to evaluate the potential human or ecological toxicity of organic compounds cannot appropriately be applied to evaluate the human and ecotoxicity potential of metals and should not be so used in the WMPT. An elemental metal like nickel should not be scored at all for Persistence (effectively receiving a score of 0) or, at most, should be given a low-end score of 1 for this parameter. (D56:5-9)

- Pentachlorophenol undergoes relatively rapid photolysis in both water and soil. Half-lives in water range from minutes (at pH 5 to 9) to a maximum of 15 days. In soil, half-lives range from 21 to 37.5 days. These data would translate into an Ultimate Survey score in the 3 to 4 (days to weeks) range based on photolytic degradation, which translates into an overall score for the persistence parameter of 2 using the fencelines in the WMPT. Thus, the consideration of recent data on biodegradation in water and soil, and data on rates of photolysis, support an overall score of 2 for the persistence parameter. (D48:21-22)

- The WMPT gives models much more weight in the process than actual measured values for key parameters that could be used to score the persistence parameter. (D48:19)

- If the WMPT model had used actual persistence data on pentachlorophenol, the outcome would have been quite different. Recent studies of biodegradation rates of pentachlorophenol in soil give aerobic half-lives of 63 days. In water, aerobic half-lives were about 5 days and anaerobic half-lives were approximately 33.8 days. These data suggest an Ultimate Survey score in the 2 to 3 (weeks to months) range based on biodegradation, which translates into an overall score for the persistence parameter of 2 using the fencelines shown in the WMPT. (D48:21)

- Persistence scores were assigned to chemicals based on model predictions, regardless of whether actual data existed or not. Chemicals that had similar BIODEG Survey Scores and BIODEG Fast Probability Scores were assigned different overall persistence scores by the WMPT. The rationale behind the different scores in unclear.

For instance, the diisobutyl ketone and hexylene glycol had BIODEG Survey Scores of 2.8624 and 2.8859, and BIODEG Fast Probability scores of 0.6308 and 0.6737 respectively. Both of these chemicals received a persistence score of 1 by the WMPT. However, methyl propyl ketone had a BIODEG Survey Score of 2.9863 and a BIODEG Fast Probability Score of 0.7913 and received a persistence score of 2. The only documented difference was the reliability score (1 for diisobutyl ketone and hexylene glycol and 2 for methyl propyl ketone). It is unclear how the reliability score was assigned. (D75:13)

- The persistence score for hexachlorocyclopentadiene is 3 based on the BIODEG Ultimate Survey Score. This is one of the parameters for which fenceline data or references are not available. We believe the following information obtained from various publications (references at end of comment) should be considered and this score modified accordingly. Hydrolysis of hexachlorocyclopentadiene has been found to be independent over the pH range of 5 to 9 (1,2). Using distilled or tap water, the hydrolytic half-life has been reported to be 16 days at 22 degrees C (3), 14 days at 25 degrees C (1), and 5 days at 30 degrees C (2). Measured hydrolysis rate constants for hexachlorocyclopentadiene in sediment suspensions at 30 degrees C range from 1.3×10^{-4} to 3.2×10^{-3} 1/min (2,4), corresponding to hydrolytic half-lives ranging from 3.6 to 3.7 days. Hexachlorocyclopentadiene in cyclohexane strongly absorbs UV light in the environmental spectrums (wavelength grater than 290 nm) (5). Strong absorption of UV light wavelength and observed rapid photolysis in aqueous solution suggests that direct photolysis may be an important fate process. Hexachlorocyclopentadiene absorbed onto silica gel underwent 46% photomineralization when irradiated with UV light for 17 hours (6). The rate constant for the reaction of vapor phase hexachlorocyclopentadiene with photochemically generated hydroxyl radicals in the atmosphere has been estimated to be 5.6×10^{-13} cu cm/mol-sec at 25 degrees C (7). Assuming an average ambient hydroxyl radical concentration of 5×10^{5} mol/cu cm (8), the half-life for this reaction is estimated to be 29 days. (D71:2)

- The persistence score for sodium benzoate is 2 based on the BIODEG Ultimate Survey Score. This is one of the parameters for which fenceline data or references are not available. We believe the following information obtained from various publications (references at end of comment) should be considered and this score modified accordingly. Under the Japanese MITI test, the theoretical biochemical oxygen demand (TBOD) for sodium benzoate was 85% in 14 days and 90% in 28 days (9). A TBOD of 93% was observed for sodium benzoate after 28 days using a seawater medium (10). (D71:2,3)

- Naled (CAS No. 300-76-5) is an insecticide produced by Valent. We would like to correct what we believe to be an erroneous assumption in the calculation of naled's chemical score. Naled is assigned a persistence score of 2, indicating moderate persistence. In fact, naled breaks down extremely rapidly. Mammalian metabolism studies on file with the EPA Office of Pesticide Programs (OPP) demonstrate that naled breaks down extremely quickly in mammalian systems. In the environment, numerous laboratory and field studies have shown naled to be short-lived. These studies, required under FIFRA, have recently been reviewed by OPP science staff in preparation for issuance of a Reregistration Eligibility Decision (RED) for naled. The draft OPP science chapter for the RED indicates that naled dissipates rapidly with half-lives of less than 2 days in field conditions. In addition, rapid hydrolysis and even faster biodegradation decrease the concentration of naled available for runoff. Similarly, naled and/or its major degradation byproducts will not persist for long. Based on an abundance of scientific evidence regarding naled's behavior both in mammalian systems and the environment, Valent recommends that the persistence score be revised to 1. Although this single change may not change any policy decisions regarding waste minimization, Valent believes that such decisions must still be made on the basis of the best available data and accurate scientific assumptions. (D72:1)

- The Chlorobenzene Producers Association has submitted extensive information to EPA concerning several of the listed chlorobenzenes in connection with the Agency's 1996 consideration of a possible test rule for persistent, toxic and bioaccumulative materials under the Toxic Substances Control Act (TSCA). The information that the Chlorobenzene Producers Association provided to the Agency in that matter, including information about persistence, partitioning to the atmosphere, levels found in surface water, and toxicity levels in aquatic organisms

is also relevant here. Appendices A, B, and C contain information relevant to 1,4-dichlorobenzene, 1,3-dichlorobenzene and 1,2,4-trichlorobenzene, respectively. (D68:7)

- EPA should re-evaluate sodium dichloroisocyanurate in the USM with this consideration in mind. The Ultimate Survey Model (USM) is used to generate a preliminary persistence score based on developing categories for aerobic biodegradation of organic compounds using the opinions of 17 experts for calibration. New compounds are then estimated using the presence of functional groups, etc. As the EPA WMPT documentation states (Appendix B, page B-3), "Model predictions are based on the presence of chemical substructures such as halogen atoms (e.g. chlorine) and hydroxyl groups." We did not have access to the EPA's specific model prediction for sodium dichloroisocyanurate, but it is highly likely that the presence of two chlorine atoms in the molecule influenced the prediction, with a bias in favor of poorer biodegradation. What was likely not considered is that sodium dichloroisocyanurate rapidly hydrolyzes to H_3CY, with the chlorine atoms replaced by hydroxyl groups [See original comments for exhibit]. The impact of replacing chlorine with the much more biodegradable hydroxyl groups would lead, in our opinion, to a higher predicted biodegradation than the 2.7131 score assigned using USM. (D59:4)

- The second biodegradation model utilized in the WMPT is a predicted measure of biodegradation. We did not have access to EPA's specific model prediction for sodium dichloroisocyanurate, but it is likely that the calculated biodegradation would be higher, assuming the same information provided above, i.e. that two chlorines are replaced (rapidly) by two hydroxyls. A value greater than 0.5 indicates rapid biodegradation (versus the current EPA prediction of 0.4714). If the new value exceeds 0.5, then EPA's procedure would reset a medium biodegradation under the USM to a value of 1 (low concern). We think that would happen if sodium dichloroisocyanurate is re-scored. Occidental Chemical Corporation, a member of the Isocyanurates Industry Ad Hoc Committee, has demonstrated that in a municipal activated sludge wastewater treatment plant, NaH_2CY is rapidly and almost completely biodegraded, with an average removal of 85% (OxyChem, unpublished data). (D59:4)

- Another modifying factor that would reduce a preliminary biodegradation score from 2 to 1 (medium to low concern), according to the WMPT guidance, is if a hydrolysis rate can be predicted to be less than 1 day at pH 7.0. The HYDRO model chosen by EPA for this purpose is restricted to esters, carbamates, halomethanes, alkyl halides and epoxides. Sodium dichloroisocyanurate is none of these, so EPA could not calculate a hydrolysis half life to use as a modifier on the persistence data. However, given the above discussion of the properties of sodium dichloroisocyanurate when dissolved in water, it is obvious that hydrolysis plays an important part in the environmental persistence of this compound. A complete review of the fate of chlorine residuals was done for the Chlorine Institute in 1990. It was concluded that the half life of chlorine/chloramine residuals discharged from municipally owned wastewater treatment plants is no more than 0.25 days, i.e. 6 hours. Sodium dichloroisocyanurate would be expected to have a half life even less because in the presence of chlorine demand, it quickly dissociates to hypochlorous acid which is consumed in the oxidation reactions. Chloramine, the form of chlorine residual discharged by most wastewater plants, would be much more persistent than sodium dichloroisocyanurate because it holds the chlorine residual much more tightly. Therefore, the half life of sodium dichloroisocyanurate when discharged to the environment will be less than 6 hours, easily meeting the hydrolysis requirement of 24 hours in the WMPT model for down rating the persistence category to low concern. It follows from the above information that sodium dichloroisocyanurate should be rated as 1 - low concern for persistence. (D59:4-5)

- The Panel also believes that EPA should not rely on models, but instead should consider actual persistence data for individual chemicals. The Panel recommends that biodegradation models be used only where actual data are unavailable, and that these models be corrected to account for well-documented abiotic degradation mechanisms and for documented inter-media transport. By ignoring actual data and eliminating these important degradation

and transport pathways from models EPA uses to assign persistence scores to many of the ranked chemicals, EPA is inaccurately ranking the hazards associated with these chemicals. (D17:ii,19-20)

- The commenter would be happy to provide persistence data for the ketones upon request. (D17:19)

- EPA should develop a rational data quality hierarchy scheme for persistence values. Measured data should be used preferentially over modeled data. (D27:78)

- Measured data for persistence should be given a higher data quality score than estimated data. (S1i:9)

- EPA's model use the BIODEG Fast Biodegradation Probability Values to reset scores only when the BIODEG Ultimate Survey Scores are >3 and ≤4. Because of lack of information concerning the BIODEG Ultimate Survey, the Methyl Chloride Industry Association (MCIA) cannot fully comment on the score of 2.9144 assigned to methyl chloride. However, MCIA questions the values assigned by this model due to the use of a narrow scale of 1-5, the inappropriate use of statistically significant figures (i.e., 2.9144 rather than 3), and the less than obvious basis for the fenceline distinguishing between medium and low persistence levels. (D53:9)

- In the WMPT scoring algorithm, great emphasis is placed on the use of persistence and bioaccumulation, yet the data used to measure these factors appear to be very scattered and inconsistent. Although the data being used in the system may be the best quality data available, it appears to be very rough. (S1e:16)

- On ecological risk, the software assigns IPBC, 3-idio-2-propynyl butyl carbamate, scores of 2 (medium risk) for persistence and 3 (high risk) for toxicity. However, the environmental fate data provided in the Re-registration Eligibility Document clearly indicate IPBC does not persist under aerobic, anaerobic and hydrolytic conditions. Therefore, the score for ecological persistence should be 1. Moreover, although IPBC is toxic to aquatic organisms, it does not persist in the environment long enough to create a hazard. Therefore, the score assigned to IPBC for ecological toxicity should also be 1. (D44:4-5)

- Pendimethalin has a persistence score in the WMPT of 3, a high level of persistence based on modeled data. However, the EPA has recently issued the Re-registration Eligibility Decision document for Pendimethalin. (This assessment included a complete review of all available information about Pendimethalin environmental fate from open literature.) The conclusion of the Office of Prevention, Pesticides and Toxic Substances was that pendimethalin dissipates in the environment by binding to soil, microbially-mediated metabolism, and volatilization. The data support a low level of pendimethalin persistence in the environment. (D36:2)

- There are several technical deficiencies associated with persistence estimates which severely limit their usefulness in the weighting process. (D37:i-ii)

- The WMPT does not address multiple factors such as volatilization, binding to substrates, and photodegradation, which greatly affect the availability of materials for exposure. (D36:3)

- Diethylene glycol butyl ether (DGBE) should have a persistence score of 1 instead of 2. The score of 2 is based on an Ultimate Survey Model of Biodegradation Score of 3.2816 and a reliability score of 2 (indicating conflicting data). How the Model gave the score and why the data are conflicting are not presented in the WMPT. DGBE, however, has been shown in many studies to be readily biodegradable and should receive a score of 1. (D45:3)

- Triethylene glycol methyl ether (TGME) has a questionable persistence score. The score of 2 is based on an Ultimate Survey Model of Biodegradation Score of 2.9393. How the Model gave the score is not presented in the WMPT. Triethylene glycol ethers are generally considered biodegradable. (D45:4)

- Methylenediphenyl isocyanate (MDI) reacts rapidly with water and does not persist in the environment. The persistence score for 4,4'-MDI should be 1, based on the well-documented reactivity of the isocyanate functional group with water. This is reflected in the updated version (1.6) of the HYDROWIN Program. (D19:i,3,4-5)

- Toluene diisocyanate (TDI) reacts rapidly with water and does not persist in the environment. The persistence score for TDI does not reflect the well-documented reactivity of the isocyanate group with water, reflected in the updated version (1.6) of the HYDROWIN Program. Because TDI cannot persist in the environment, the persistence score should be 1. (D19:ii,3,10-11)

- The WMPT inappropriately relies on biodegradation models that have not been made available for public review and comment and for which EPA has provided inadequate information to permit an understanding of how the numbers were developed and what they mean. (D20:i,3)

- The WMPT ignores high quality persistence data that have been published in the peer reviewed literature or that have been developed or used by other EPA offices. For example, the WMPT evaluation of persistence does not consider recent biodegradation information regarding nonylphenol (NP) and nonylphenol ethoxylate (NPE) that has been provided to EPA. (D20:i,3,13-14)

- The approach used to develop scores for persistence is poorly documented. Table B-2 does not completely represent what must be evaluated in the persistence determination. The attached flowsheet, "Overview of the Procedure Used by EPA in WMPT to Develop the Persistence Subfactor," reflects the best assessment. (D30:8)

- The classification of metals for persistence is again confusing and raises potential for misinterpretation. It implies that elemental metals are classified as "3", while other categories of metals are not classified. Yet, it is generally organically complex metals that are of greatest concern rather than elemental forms. As a result, the WMPT treatment of persistence data needs rigorous review and substantial revision. (D30:8)

- Zinc, of course, is a natural element, naturally present in soil, rocks and water throughout the world. As such, zinc will persist in the environment and is wholly different from manmade chemicals. (D50:4)

- Because the American Zinc Association (AZA) believes this notion of persistence has no place in any legitimate analysis of risk posed by natural elements such as zinc, and because EPA's actions in compiling the List fly in the face of the body of science and worldwide agreement on the inappropriateness of using persistence in such an analysis, AZA commissioned the attached review and analysis by Dr. Peter Chapman of EVS Environment Consultants, which review is incorporated by reference at this point. (D50:4)

- As the Agency can see, EPA's use of persistence in the List is not only scientifically unsound, but is also contrary to international consensus on the issue, including consensus in some fora in which EPA has participated. Finally, EPA's own documents in the docket concede that "chemical persistence subfactor scores were set too high for any elemental metals." (D50:5)

- Bioavailability of zinc following ingestion varies markedly as a function of homeostatic control mechanisms. As is true for virtually all essential trace elements, the uptake of zinc into the body following ingestion is carefully regulated by a variety of physiological mechanisms. It is extremely difficult to conceive of plausible scenarios in which environmental contamination or waste disposal could result in human exposures which would be excessive. Indeed, environmental exposures would have great difficulty exceeding the recommended daily allowance for zinc, much less the RfD. Thus, zinc and all elemental metals for that matter have been incorrectly assessed in the List. As a result, any actions to reduce zinc in wastes because of concerns over persistence will be misaimed, and resources directed thereto will be misallocated. The List needs to be thoroughly revised. (D50:5)

- If EPA determines that methyl chloride must be included on the WMPT, at a minimum, EPA must ensure that the score assigned is accurate. As documented evidence indicates that methyl chloride does not persist in aquatic environments, the persistence score assigned to methyl chloride should be reduced accordingly. The WMPT assigned a medium level of concern persistence score of 2 to methyl chloride based on the BIODEG Ultimate Survey Score. According to EPA, "[p]ersistence indicates how long a chemical is expected to exist in the environment and, thus, be available for exposure." The WMPT biodegradation "models focus on releases in water" and do not address the potential chemical partitioning through volatilization from water into air, atmospheric oxidation, or soil adsorption. Lack of readily available background materials hinders meaningful comment on EPA's application of these models to methyl chloride. Nonetheless, evidence indicates that this score is inaccurate because it fails to account for the fact that methyl chloride is a gas at ambient temperatures and that it rapidly volatilizes in water.

- EPA should use measured data, where available, in preference to modeled data to assess a compound's potential to persist in the environment. This is particularly true in the case of the persistence, because no documentation is available for the BIODEG Ultimate Survey Model (USM), making the assumptions and results of that model unreviewable. For example, For several of the aryl phosphates, the draft WMPT includes a "BF" value from EPA's BIODEG SUM database. The "BF" value indicates that the chemical is rapidly biodegraded. If the reliability code was a 2 (two test results), the draft WMPT relied on the Ultimate Survey Model (USM) prediction instead of the BF score, resulting in a score of 2 or 3. A reliability code of 2 indicates that there are at least two biodegradation studies on the chemical, with the weight-of-evidence supporting a "BF" value for the chemical. Given that all aryl phosphates in the BIODEG SUM database consistently received a "BF" rating, they all should be assigned a low persistence score. (D21:i, 14)

- Although the oxo process chemicals properly received the lowest possible scores for persistence and bioaccumulation, information in the WMPT should be revised to incorporate actual persistence and bioaccumulation data, rather than including only modeled data. (D25:14)

- Persistence is determined by a Biodegradation Ultimate Survey Score (BUSS) generated by an internal EPA model, which is not subject to verification. (D24:2)

- There is no available documentation explaining how the persistence score of 2 was derived for Octamethylcyclotetrasiloxane (OMCTS) from predictions made using the BIODEG Model. It is clear that the score cannot be accurate because it fails to consider OMCTS's high volatility and natural partitioning to air where OMCTS then easily photodegrades (high-life of 3 hours to 6 days). The User's Guide notes that any chemical substance that has an estimated biodegradation rate in water of hours or days clearly is a "low" persistence substance and should be assigned a persistence score of 1. Thus, even under the draft WMPT model, the persistence score for OMCTS should be 1 rather than 2. (D49:2, 8-9)

- EPA is inaccurately scoring the hazards associated with many of the chemicals by: (1) eliminating important degradation and transport pathways from the "data sources" EPA used to assign persistence scores, (2) not using data obtained from costly and time-consuming studies internationally designed to understand the full degradation scenarios of the chemical substances used, (3) using models that favor chemicals with little data over well-characterized chemicals, and (4) using extrapolations or predictive models rather than actual data. (D49:11, 24)

- Quantitative or actual data should take precedence over extrapolations from actual data, which, in turn should be given a higher priority than qualitative data or model predictions. In particular, the WMPT develops a preliminary persistence score based on model predictions derived from either the Ultimate Survey Model or the estimated probability of rapid biodegradation as predicted by the Non-linear Model of Rapid Biodegradation. Measured biodegradation data may be used, but only to adjust preliminary persistence scores. (D49:14, 24)

- The draft WMPT is too simplistic to factor in the environmental fate of many chemicals. It accounts for certain chemical and physical characteristics, but fails to account for all factors essential to accurately evaluate environmental fate, such as degradation and transport pathways. The draft PCL persistence and bioaccumulation scoring for two silicones—Octamethylcyclotetrasiloxane (OMCTS) and trichlorophenylsilane—reveal significant deficiencies in the draft WMPT model. These scorings fail to account for volatility, water solubility, and photodegradation characteristics of these compounds. As a result, the scorings do not reflect scientifically valid characterizations. (D49:2, 7, 10-11, 14)

- Most of the P and B data are from models instead of from direct measurements, a relatively inaccurate way to evaluate P and B. Modeled P and B data, particularly the octanol-water partition coefficient, do not consider metabolism or photodegradation. (D32:4)

- There is an over-reliance on modeling data for B and P. For example, the persistence score for tricresyl phosphate (TCP) is 2 based on the BIODEG Ultimate Survey Score, yet other BIODEG predictions, the Aerobic code, and substantial experimental evidence suggest that TCP is rapidly degraded. Therefore, TCP should be assigned a P score of 1. (D32:10)

- If a chemical is ranked 3 in the B or P category, the chemical is stigmatized as being "the worst" for that characteristic even though such a characterization is not necessarily true. Persistence is not necessarily a negative chemical characteristic since more stable chemicals often have a more limited ability to react with biological systems. Many "persistent" chemicals, such as metals, may not be very biologically available; however, when the WMPT ranks them as 3 in terms of their persistence, that number is added twice (once for the human health risk potential and again for the ecological risk potential)—resulting in a higher and, therefore, "worse" score than chemicals that are not as persistent but which may be more biologically available. WMPT, therefore, unfairly characterizes persistent metals as bad chemicals even though they may be very inert in the environment. (D54:2)

- The persistence factor in the WMPT diethyl phthalate (DEP)arts from sound scientific principles by relying on predictive models rather than measured data. (D27:14)

- The WMPT approach of using only modeled data inappropriately discounts measured data. The WMPT should use measured data to determine persistence scores. This is particularly important since there is little documentation available for reviewing the BIODEG model used in calculating these scores. Therefore, the BIODEG model cannot be used as a source of "high" quality, valid persistence values. (D27:27-28)

- Di-n-octyl phthalate (DnOP), Di(2-ethylhexyl)phthalate (DEHP), Di-n-hexyl phthalate (DnHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diethyl phthalate (DEP), and Di-(2-ethylhexyl)adipate (DEHA) have been assigned a persistence score of 1, which commenter agrees with. (D18:54, 61, 63, 69, 74, 80, 90)

- The WMPT uses inferior modeled predicted data generated using BIODEG for phthalate esters. Measured data should be used instead; a failure to do so is bad science. Use of predicted over measured data has resulted in high scores for many phthalate esters where the measured data indicates low persistence. Measured data for the biodegradability in the literature is sufficiently uniform that all phthalate esters in the WMPT should receive a low persistence score even if measured data are not available for a specific phthalate ester. (D18:ia, 3, 36-37, 38) In particular, persistence scores should be changed for the following phthalate esters:
  -Diiodecyl phthalate (DIDP), from 2 to 1. (D18:47)
  -Diisononyl phthalate (DINP), from 2 to 1 for CASRN 28553-12-0. (D18:50)

- Diallyl phthalate (DAP) should be assigned a low persistence score. (D18:76)

- Persistence scores in WMPT are based solely on hydrolysis and biodegradation potential. Other biodegradation processes may also be critical in determining the overall persistence of hydrocarbons. For example, photolysis serves as the primary degradation route in surface waters of many of the three to five ring PAHs (Neff, 1979; Howard et al., 1991). Atmospheric photodegradation is particularly important to hydrocarbons since the atmosphere serves as the primary compartment to which hydrocarbons are released via combustion reactions. Atmospheric oxidation potential can be determined using commercially available QSARs (e.g., AOP Model) (Atkinson, 1988; Meylan and Howard, 1993). (D29A:15)

- For BTEX and two or three ring PAHs, the Ultimate Survey Model yields a score in the two to three range, a moderate bioaccumulation potential. However, this characterization is not consistent with measured data from standardized biodegradation tests. Numerous literature studies confirm the highly biodegradable nature of BTEX and lower molecular weight PAHs in soil and water (Urano and Kato, 1986; Tabak et al., 1992; Howard et al., 1991; Harris, 1996). This conclusion is further supported by the predictions obtained from the non-linear probability model included in WMPT, which indicates a high biodegradation likelihood. Curiously, the non-linear probability model predicts that acenaphthylene would have the lowest biodegradation probability, but this compound is correctly characterized as highly biodegradable in WMPT scoring. This clearly indicates that BTEX should be assigned a low persistence score based on high biodegradation potential. (D29A:15,16)

- Since the Ultimate Survey Model has not been subjected to an independent validation study, the utility of this tool for priority setting is questionable. (D29A:16)

- The Ultimate Survey Model which is used to predict estimated biodegradation time for persistence is based on expert opinion. Therefore, greater emphasis appears to be placed on the use of expert opinion (i.e., the Ultimate Survey Model) over the use of actual measured methods (data) (i.e., BIODEG SUM). (S1e:16)

- Measured biodegradation data is preferable to estimated (modeled) data. The biodegradation models are based on the structure of the chemical, and most estimate biodegradation in water. The models are excellent for chemicals highly recalcitrant or highly biodegradable, but not for chemicals in between. (S1i:36)

- Regarding the use of predicted data in developing bioaccumulation and persistence scores, it seems that measured data may be more reliable. (E1:8)

- Silver, like other metals, is naturally occurring in the earth and does not biodegrade. In this respect, silver is wholly different from manmade chemicals. For these and other reasons, the use of "persistence" to rank silver's risk is inappropriate. The Silver Institute hereby adopts and incorporates by reference the comments on this point submitted by the American Zinc Association and EVS Environmental Consultants. (D51:4)

c. Fenceline Values

- It is unclear how the Agency has selected levels of persistence that it believes are levels of concern. What is the rationale for the particular levels selected for use in the Tool? In the absence of a full discussion about why particular levels of persistence are of concern to EPA from the perspective of public health or ecological protection, it is impossible to evaluate thoroughly the draft waste minimization program. A thorough evaluation of this issue in the context of notice and comment rulemaking would facilitate sound scientific decision-making. (D68:5)

- Fenceline data need to be provided for all parameters. Parameters such as the BIODEG Ultimate Survey Score are given a specific value; however, fenceline data are not provided to compare the given values. No fenceline values are provided for any of the persistence parameters. (D71:1)

- EPA has provided limited information regarding the basis and criteria on which it relied to establish the fenceline values for the various parameters and has not adequately addressed the evaluation of "borderline" chemicals to ensure that they are appropriately characterized. (D20:i,3)

- EPA's exposure factor should consider the bioavailability of chemical substances. (D27:78-79)

- EPA should revise their scoring system to account for bioavailability, to provide greater discrimination between chemical scores, and to apply ecological risk estimates only when appropriate. (D29:cover2)

- In general, any substance which is persistent in the absence of toxicity and bioaccumulation is considered inert and should be viewed favorably in terms of waste management issues. Specifically, many dyes may be persistent by design but are without any remarkable toxicity. (D41:2)

- Dyes such as indigo and Basic Violet 3 are water soluble products and should not have a persistence rating of 2 or 3. (D41:2)

- The Chemical Data Summary assigns a Persistence Score of 3 to beryllium. Since all metals are natural occurring substances, it appears unreasonable to assign them a Persistence Score as that score contributes to a chemical's composite toxicity score. (D15:7)

- EPA (1997b) is correct in their definition of risk, in particular that risk is a function of toxicity and exposure. They are incorrect in stating, for persistence, that "the greater the persistence of a chemical, the greater the potential for human or ecological exposure to the chemical." They are also incorrect in stating, again for persistence, that "Persistence is a more important criterion for assessing risks of long-term (i.e., chronic exposures) than short-term exposures"(cf. Chapman, 1996). Nevertheless, zinc, an elemental metal and an essential metal is assigned the highest possible persistence score, 3 out of a possible 3. The end result is that, when one scores zinc following EPA (1997a,b), its overall chemical score is 13 out of a possible 18. (D50:3b)

- The score and the use of persistence for classifying zinc as hazardous bear no relationship to hazard or risk (i.e., to what the EPA is trying to assess). There is no question that zinc (and other elements) are persistent. If they were not, life as we know it would not exist. In this regard, elements and metals such as zinc differ from synthetic organic chemicals which can appropriately be classified according to hazard based on persistence. In general, the degradation (i.e., nonpersistence) of synthetic organic chemicals reduces the extent to which organisms may be exposed to them and thus reduces hazard and risk. For example, after 100 days following its introduction into the aquatic environment, a synthetic organic compound with a half-life of 100 days will only be present at half the concentration which was originally introduced. (D50:3b)

- Persistence is an entirely inappropriate measure to determine the hazard of elements and metals such as zinc. Elements and metals such as zinc are by definition persistent; they are intrinsically not degradable. They are a fundamental part of the Earth's crust and form the natural building blocks of soils, sediments and, in the case of essential metals such as zinc, organisms. Thus, the persistence of zinc, in contrast to synthetic organic substances, results in environmental benefits rather than harm.. (D50:3b)

- EPA themselves recognize the inappropriateness of persistence for characterizing hazard in risk. Specifically, in Appendix B of EPA (1997b p. B7) it is noted that persistence cannot be determined in the same way for metals and metal-containing compounds as for organics and, further, that "WMPT chemical persistence subfactor scores were set too high for any elemental metals." EPA (1997, p. B8) also acknowledge that "...metal ions may potentially complex with other substances to form precipitates ... [which can be] relatively innocuous..... (D50:4b)

- A number of aromatic hydrocarbon solvents (e.g., toluene, benzene, xylenes) are assigned persistence scores of 2. The measured biodegradation of each of these compounds is roughly equivalent to biodegradation measured for aliphatic hydrocarbons that are scored by the WMPT as 1. In reality, given their volatility and biodegradability, all hydrocarbons should be considered non-persistent, and given a score of 0. (D24:2-3)

- There is considerable loss of discrimination among chemicals because the algorithm uses biodegradation almost exclusively for persistence. Those chemicals that hydrolyze, photolyze, and oxidize are penalized in persistence scoring unless they also biodegrade. (D31:16)

- The persistence factor in the WMPT diethyl phthalate (DEP)arts from sound scientific principles by leaving out factors like oxidation and photolysis. (D27:14)

- Persistence is not a useful criterion for assessing the risk potential of metals and should be abandoned. Evidence of how including persistence results in mis-ranking of metals can be seen in the Draft PCL. Chromium (score 13), nickel (score 14), copper (score 13), and zinc (score 13) are ranked higher than deadly chemicals such as cyanide (score 9) and mustard gas (score 11). This problem is amplified by the double counting of persistence. The public will receive the impression that nickel coins are more risky than pellets of cyanide or mustard gas. (D9:3,5; D10:3,5)

- Persistence refers to the failure of a substance to readily biodegrade. Organic compounds are biodegradable, and, therefore, persistence is a relevant parameter for comparison of risk potential among organics. In contrast, inorganics (such as metals) are not biodegradable and persistence is not a useful measure. Metals are fundamental building blocks in the environment, including soils, sediments, and organisms, and their persistence is often environmentally beneficial rather than harmful (e.g., copper is essential for human and plant life). (D9:4; D10:3-4)

- Persistence scoring must be modified to (1) consider the transport of a chemical substance from one environmental media to another, and (2) consider abiotic chemical degradation through hydrolysis, photo-oxidation, photolysis or reduction. (D49:2, 7)

- The WMPT ignores atmospheric degradation for organic chemicals (yet this is the predominant degradation process), and it ignores pathways such as adsorption to soils. For example, volatile organic compounds like toluene and xylenes received inaccurate scores of 2 for persistence; these compounds rapidly photooxidize when released to air. PAHs are subject to aqueous photolysis, which the WMPT does not consider. (D27:43-44)

- Chemicals that degrade abiotically or volatilize quickly are treated as equivalent to recalcitrant, non-degradable compounds. As a result, the scoring system is virtually meaningless for evaluating impact or risk in the environment for these chemicals. (D30:8)

- Ethylene glycol ethers and propylene glycol ethers are readily biodegradable and should not be included among any list or ranking of PBT chemicals. (D45:2; D46:1)

- The WMPT may rely inappropriately on biodegradation models to evaluate persistence. Readily available background materials on BIODEG do not permit a meaningful review of the application of these models to individual compounds. Therefore, the commenter was unable to provide comments regarding the validity of the assumptions or completeness and accuracy of the data underlying the application of these models. Nonetheless, it appears that the model predictions provide only a very rough indication of the relative persistence of the chemicals evaluated. The Fast BIODEG Probability predictions support low biodegradation scores for nonylphenol (NP), nonylphenol ethoxylate (NPE), and octylphenol ethoxylate (OPE), and suggest that the application of the models to these compounds should be scrutinized carefully. (D20:11-12)

- Persistence scores are based solely on biodegradation, leaving out non-biological degradation processes such as hydrolysis, photolysis or oxidation. As the primary degradation pathway for hydrocarbons is photolysis, the WMPT persistence is *ab initio* incorrect. (D24:2)

- The persistence factor in the WMPT does not consider partitioning of a chemical into the media of concern (air, water, soil, or sediments). (D27:42-43, 78)

- The persistence component overemphasizes the importance of biodegradation as a fate process. The persistence model needs to directly take into account all major environmental fate processes including hydrolysis, photolysis, and volatility coupled with atmospheric reactivity. (D37:ii)

- The risk score and rank that EPA has given 2,4,4'-trichloro-2'hydroxydiphenyl (i.e., "risk" score of 14 out of 18, and rank 86 out of 800) is inaccurate. Based on a preliminary review, the extensive database on triclosan Ciba has determined that the overall human and ecological "risk potential" score for triclosan should be lowered to 14 for the following reasons: (1) monitoring of waste water treatment plants (WWTP's) in high use areas show typical influent concentrations of triclosan to be 5-10 ppb with typical removal of 95-97 percent; (2) continuous Activated Sludge Removal Studies run at 10 and 40 ppb resulted in 95-99 percent total removal of triclosan; (3) in two independently conducted soil biodegradation studies [using (a) 40 mg/kg and (b) 200 mg/kg, respectively] extensive biodegradation was demonstrated: (a) 99% loss of parent and 50% mineralization in 577 days and (b) 80-85% loss of parent and 18% mineralization in 64 days; and (4) because triclosan biodegrades aerobically and is photolytically instable, the compound does not persist in the waste stream or receiving waters. (D13:4,5)

- All relevant degradation factors are not considered. The WMPT does not account for processes like photolysis, atmospheric oxidation, oxidation-reduction reactions, and polymerization. For example, the WMPT neglects polymerization of toluene diisocyanate and ignores dissociation of metals into ions or the formation of inert precipitates. These methods are overly simplistic, lead to inaccurate and misleading descriptions, and can lead to dramatically inconsistent results. EPA should assess these factors in the WMPT. (D27:42-43, 78)

- EPA does not make clear the rationale underlying the fenceline values it established, and this criticism also is made of the UCSS by the Science Advisory Board. For persistence and bioaccumulation, EPA set fencelines to give a 1:1:1 distribution (high, medium, low) for a sample set of chemicals. For toxicity (RfD data), the fencelines were set to give a 1:2:1 distribution. No explanation is given as to why these are the appropriate distributions, or why they differ for the toxicity factor vis-à-vis the persistence and bioaccumulation factors. (D20:6)

- To ensure that chemicals are not inappropriately categorized as medium concern instead of high concern due to one or more misplaced fencelines, EPA should conduct a sensitivity analysis on fenceline values. (E1:8)

d. Consideration of Biodegradation and Degradation Byproducts

- Phthalic anhydride rapidly hydrolyzes to phthalic acid, and should therefore have a low persistence score. (D18:86)

- The WMPT does not provide a comprehensive assessment of the environmental fate for many chemicals. The WMPT does not consider all the relevant chemical and physical characteristics that are essential to accurately evaluate exposure potential (e.g., persistence and/or bioaccumulation in water are not relevant if a chemical partitions to the atmosphere or undergoes rapid hydrolysis). (D35:5)

- The emphasis on Bioaccumulation and Persistence needs to be modified and other pathways for degradation/sequestration of the chemical in the environment should be considered including volatilization, photolysis and adsorption. (B34:6)

- There is no provision for incorporating measured biodegradability data into the persistence score or waste volume into the risk score. (B34:6)

- The WMPT fails to provide a comprehensive evaluation of a chemical's environmental fate. This failure could result in incorrect scoring by the WMPT. For example, the ranking scores given to octamethylcyclotetrasiloxane (OMCTS) and trichlorophenylsilane are incorrect and developed without assessing their environmental fate. (D35:2; D35:5-6; D35:6; D35:1)

- WMPT does not seem to have the ability to consider the formation of toxic degradation byproducts when ranking chemicals. However, degradation byproducts could be more toxic than the parent chemicals, and this is not reflected in the scoring of the parent chemical. A related concern is that chemicals that are predicted to hydrolyze might be assigned a lower persistence score, yet be more toxic due to their ability to be taken up by an organism. (E1:9)

e. Consideration of Persistence in Other Media

- The WMPT focuses on the water compartment and does not address chemical partitioning to other compartments. (D48:20)

- Because EPA has failed to account for partitioning to the atmosphere or for various types of atmospheric degradation, the persistence scores are completely meaningless to the extent that they apply to substances that largely partition to the atmosphere. In the case of the chlorobenzenes, nearly all releases evaporate and degrade in the atmosphere. A scoring system that ignores atmospheric degradation renders arbitrary any resulting persistence scores for these compounds. (D68:5-6)

- Of particular importance is the information provided to the Agency concerning partitioning of the chlorobenzenes among environmental media. As noted above, EPA's persistence models do not take into account abiotic degradation through hydrolysis, photo-oxidation, photolysis or reduction. The commercially available chlorobenzenes—chlorobenzene through 1,2,4-trichlorobenzene—rapidly evaporate from aquatic media. Therefore, EPA's persistence scores are inappropriate for these compounds, failing to account for their partitioning and atmospheric degradation characteristics. Appendix A contains 1,4-dichlorobenzene-specific information, including reported bioconcentration factor values, reported Log K_{ow} values, distribution figures and available exposure and ecological effects data, as presented by the Chlorobenzene Producers Association to the Agency's Test Rules Development Office. It can easily be seen that the distribution of 1,4-dichlorobenzene in the environment is nearly all in the air. (D68:8-9)

- The User's Guide states (at B-6) that there is no satisfactory model for air persistence. The model of Atkinson, as part of the SRC QSAR, may be the most universally used and accepted. Its predictions are acceptable for VOCs and for those SVOCs for which there are data to verify the model. However, for some of the SVOCs and compounds with unique functional groups (e.g., NO_2), the results may not be acceptable. (D30:8)

- Assessing the risk and risk of metals such as zinc requires consideration of three separate transformation processes in the aquatic environment (Chapman, 1996): when a metal first enters the aquatic environment solubilization occurs which increases bioavailability; however, the ultimate fate of metals in water is association with sediments, which will make them less bioavailable (i.e., persistence reduces risk the reverse of the case for organic chemicals); resolubilization will increase bioavailability but not to its initial level (i.e., prior to association with sediments).

Even if the sedimentary environment is disturbed (e.g., due to dredging, or storms), only a small portion of the metal contained in the sediment is released (Zhuan et al., 1994; Foerstner, 1995). (D50:4b)

- Persistence of zinc in aquatic systems bears no relationship to present or future bioavailability and toxicity (i.e., to hazard and risk). The same is true of terrestrial systems. (D50:4b)

- Metals in soils tend similarly to have low bioavailability and toxicity in large part due to their absorption onto clays and organic matter in the soil matrix (Lee et al., 1996). Even if, under particular environmental conditions (e.g., acid soils), metals such as zinc may be mobile, they are often accumulated in environmental compartments in forms which are chemically stable under the prevailing conditions and thus largely biologically unavailable. Hence the need to supplement agricultural soils with essential elements such as zinc which, though persistent, is not biologically available and hence does not pose a toxicity hazard due to excess but rather due to deficiency. (D50:4b)

- High concentrations of an element and essential metal such as zinc accumulating in the environment do not pose a chemical hazard if they are essentially inert for centuries or longer time periods, within the normal fluctuations of environmental conditions (Chapman et al., 1996). (D50:4b)

- EPA has previously recognized that for methyl chloride "volatilization is the most important removal mechanism from aquatic media." Reports prepared by ATSDR further recognize that when present in water, methyl chloride will volatilize rapidly. In fact, ATSDR noted that data regarding biodegradation in water may be irrelevant due to possible rapid volatilization from aqueous media. Considering these facts, it is clear that methyl chloride does not persist in water. Thus, the persistence score assigned to methyl chloride should be the lowest score possible. This conclusion is consistent with EPA's acknowledgment that a fast biodegradation rate should correspond to a low persistence score. EPA has indicated that chemicals expected to degrade in days or less should be designated as low persistence. Specifically, "[a]n estimated model probability greater than or equal to 0.5 indicates a rapid biodegradation rate." The BIODEG Fast Biodegradation Probability Values relied on by the WMPT designated a rate of 0.608 for methyl chloride, confirming the rapid degradation rate of the small amount, if any, of methyl chloride that would remain in water. Thus, EPA's own analysis confirms methyl chloride's low persistence level in water. Rapid biodegradation and volatilization ensure methyl chloride's immediate disappearance in water. Thus, methyl chloride should receive a persistence score of 0. If EPA does not change the current scoring system, methyl chloride should receive a persistence score of 1. (D53:7-9)

- Data on chemical partitioning to various environmental media must be considered directly in determining the persistence factor and should be incorporated into the current model. There is no basis for delaying the incorporation of this information or for considering it in a supplemental rather than a direct manner. (D49:7)

- The persistence score of 2 assigned to trichlorophenylsilane appears to be based solely on the BIODEG Model and the predicted log K_{ow}, without taking into account actual data on the hydrolysis of trichlorophenylsilane. Moreover, the persistence score of trichlorophenylsilane should be 1 instead of 2, because it hydrolyzes in seconds. According to the User's Guide, "[a] predicted chemical hydrolysis half-life value at pH 7 of less than 1 day was used to reset a medium persistence subfactor score based on ultimate survey and non-linear model data to low." (D49:2, 10-11)

- Data that are most appropriate to use/treatment/disposal should be used. For example, if a chemical is released to the air, photodegradation is important to consider for persistence. (D32:6)

- In order to account for persistence in other media, EPA should use the following formula for calculating the persistence score: Persistence of X = ((% of X in Air) * (Persistence score in Air) + (% of X in Water) *

(Persistence score in Water) + (% of X in Soil) * (Persistence score in Soil) + (% of X in Sediments) * (Persistence score in Sediments)). Other models could account for atmospheric oxidation and partitioning. (D27:78)

- WMPT should be modified to rank chemicals that partition to air more accurately. WMPT currently uses biodegradation and hydrolysis to determine persistence. Two other models might be used which would account for the portion of chemicals that partition to air. The EQC model estimates the percentage of each chemical partitioning into air, water, soil, and sediment, allowing persistence factors to be weighted based on the media of concern. The necessary data for the EQC model includes water solubility, vapor pressure, log K_{ow}, and molecular weight. If data are not available, models can be used to estimate the parameters. There is a system which multiplies the percentage of a chemical partitioning to air, water, soil, and sediments by the persistence of that chemical in air, water, soil, and sediments. In comparing the WMPT to this system, the results are close to the same for chemicals with the highest scores (17-18). With lower scores, however, the results are frequently different. The AOP WIN model is used to provide persistence information for chemicals in air, water, soil, and sediments, using indirect photolysis and oxidation data. The AOP WIN model does not capture simple chemical oxidation and the data in this model are based on the structure of the chemical. To account for the differences in persistence and biodegradation between air, water, soil, and sediments, incorporate the EQC model to partition the chemical and use the AOP WIN model, combined with the BIODEG and Hydrolysis models, to provide persistence information for the chemical in air, water, soil, and sediments. (S1i:10,37)

- EPA receives or has access to biodegradation data for anaerobic environments. While anaerobic data might not be appropriate for surface water environments, it is necessary for sediments. If the data were partitioned to soil and sediments as well as to air and water, the anaerobic biodegradation data would be useful. (S1i:12)

- EPA should consider developing and incorporating partitioning data, such as that used in the CalTox model, along with persistence and bioaccumulation data to enhance the tool. The partitioning data will provide a better sense of which exposure routes are of greatest concern for a specific chemical. Although partitioning data is unavailable now, it should be integrated into WMPT as it becomes readily available. The CalTox model should be used as an example of the type of baseline data that should be available for all chemicals. (S1e:15)

- Consider multiple degradation pathways as appropriate for the given chemical. Identify which media the chemical is likely to partition to and then assess the degradation within that media. Keep in mind that the more multi-media and pathway specific the tool becomes, the more it resembles a risk assessment tool rather than a screening tool. (S1e:16)

- The WMPT does not consider the environmental compartment to which the chemical is released and the potential for subsequent multi-media transfer. Such considerations are important determinants of overall persistence because half-lives in different environmental compartments can differ drastically (Mackay, 1991). High molecular weight PAHs have relatively long half-lives in soil but very short half-lives in air, while the opposite is observed for BTEX (see Table 7 of comment). Persistence depends on the release scenario and multi-media fate. (D29A:17)

f. Other

- Bioavailability is not considered despite the dependence of toxicity on this factor. (D27:18)

- The WMPT unfairly scores the persistence of metals without regard to the bioavailability of the metal ion. (D43:i)

- Participants in the 1996 Canada/European Union Technical Workshop "agreed that biodegradation is not suitable as a criterion for the evaluation of the environmental hazard of inorganic substances and that the ... OECD Test Guideline for ready biodegradability should not be used in testing such substances." What is relevant is whether,

under the specific environmental conditions involved, the metal is or will become bioavailable in a form that is capable of interacting with or passing through a biological membrane at a concentration that would be toxic to the receptor organism." That, in turn, depends on a number of factors involving the characteristics of the metal or metal compound (e.g., its solubility or transformation characteristics) and of the environmental medium in which it is present (e.g., factors that affect the transformation and removal of bioavailable cations from the environment)." Among the most important of these parameters (depending on the environmental medium involved) are: pH; Eh (oxidation/reduction redox potential); Water hardness, Alkalinity; Ionic strength; Presence of suspended particulate matter and organic carbon; Temperature; Presence of complexing inorganic ligands; Presence of inorganic oxides of Fe, Mn, Al, and Si; Presence of sulfides; Presence of organic chelating agents; Presence of methylating agents; and Cation exchange capacity. (D56:2, 5-9)

- If EPA does not remove methyl chloride from listing under the WMPT and PCL, EPA should (1) revise the overall rank of 9 assigned to methyl chloride, which is based on an inaccurate and overweighted persistence score, and (2) indicate that methyl chloride is not a priority for waste minimization. (D53:3)

- Persistence is only of concern if a substance is bioavailable. Thus, bioavailability should be the principal parameter by which to assess the risk potential of a substance. Bioavailability, in turn, depends on solubility, which can vary from one compound to another. For example, solubility varies significantly among copper-containing compounds, which include insoluble particulates, soluble inorganic and organic complexes, and various oxidation states of copper ions. Accordingly, a proper risk assessment must differentiate the various copper compounds. (D9:4,5; D10:4,5)

- EPA's approach assumes that increased persistence translates into increased exposure potential. While this may sometimes be the case, high persistence may be the result of low bioavailability for degradation, which also translates to low exposure potential. Although PAHs persist in field sediments, they are significantly less bioavailable than other chemical classes. It is hypothesized that this is due to the inclusion of PAHs in soot particles (McGrody et al., 1996; 1996), illustrating that the form of the chemical in waste influences bioavailability, affecting a compounds persistence. Moreover, assessing persistence in the absence of bioavailability considerations may be misleading. (D29A:17)

4. Bioaccumulation Scoring

a. Data Quality Hierarchy

- While it appears that EPA has included some measured BCF/BAF data in WMPT, these data were not used in scoring. It is also impossible to critically review the chemical-specific BCF and BAF values in WMPT since these values were obtained from an internal EPA database. Furthermore, critical information (i.e., measured vs. Predicted, parent compound or parent plus metabolites, species) are not provided. (D29A:13)

- EPA's IRIS database system should not be used for BCF data; this database provides no references, has not been subject to notice and comment, and contains flawed and inaccurate data. (D27:44)

- The WMPT approach also fails to recognize that the superiority of bioaccumulation factor (BAF) values over bioconcentration factor (BCF) values has not been validated and is questionable. First, BAF values are measured in the field and can have a great deal of variability depending on the site, organism, etc. Generally, BAF and BCF values are also the same for substances with BCF values less than at least 5,000. Therefore, it is recommended to use BCF values measured consistently in controlled and standard laboratory conditions over measured BAF values, particularly for compounds with BCFs less than 5,000. If the BCF is greater than 5,000, the score is already a "3." (D30:8)

- The WMPT relies on estimated log K_{ow} measurements to develop bioaccumulation scores even if measured log K_{ow} values are available. Quantitative or actual data should take precedence over extrapolations from actual data, which in turn, should be given a higher priority than qualitative data or model predictions. (D49:14, 24)

- The data quality hierarchy for bioaccumulation is flawed because it inappropriately prefers predicted log K_{ow} values to actual measured log K_{ow} and actual measured bioaccumulation data. (D20:i,3,7-9)

- EPA could explore the idea of indicating in the documentation or the software that the user could choose between using the log K_{ow} or BAF or BCF. EPA could list the type of indicator organisms which would appropriately be used in each EPA region so that a facility could measure BAFs and BCFs to challenge log K_{ow} results. This might be a longer term fix to the tool. (S1i:11)

b. Use of Measured vs. Predicted Data; Data Sources and Accuracy

- DEHA's bioaccumulation score in the draft WMPT is 3, based on a modeled log K_{ow} of 8.12. As discussed in section III.D., the log K_{ow} is a poor predictor of phthalate ester bioaccumulation potential. This also applies to adipates such as DEHA. Measured data demonstrate that DEHA has a low potential for bioaccumulation or bioconcentration. Felder et al. (1986) report a measured BCF for DEHA of 27. The authors suggested DEHA probably was being metabolized. Since the test monitored ^{14}C-radiolabeled DEHA, so that both parent DEHA and its metabolites would have been measured, DEHA's actual BCF is likely to be much lower than the reported value of 27. Therefore, EPA should assign DEHA a low bioaccumulation score. Under the draft WMPT methodology, its score should be 1. (D18: 90)

- Measured log K_{ow} values are available for many compounds on the draft prioritized chemicals list, including 4-NP, NPE and OP. Indeed, EPA's RM1 Document reported measured log K_{ow} values for 4-NP to be in the range of 3.8 to 4.77. RM1 Document at 1 (Table 1). A measured log K_{ow} for 4-NP of 4.48 also is published in peer reviewed literature. See Ahel and Giger (1993). Similarly, Ahel and Giger reported measured log K_{ow}s of 4.17, 4.21 and 4.20 for NPE 1, 2 and 3, respectively. The measured log K_{ow} values are in significant contrast to the EPA-calculated values for NP, 4-NP and NPE of 5.76, 5.92 and 5.58, and all are below the high concern scoring

fenceline of 5.0. These measured values of good quality should take precedence over the calculated values. Values based on predictions should be used only in the absence of actual data. (D20:8-9)

- The solubility of NPE increases with increasing ethoxylate chain length. The higher mole ethoxylates of NP are freely water soluble. Because the higher mole ethoxylates are mixtures of oligimers, they cannot be described by a single log K_{ow} number. Nonetheless, because log K_{ow} decreases as water solubility increases, their log K_{ow} values are expected to be very low. (D20:9)

- For OP, Ahel and Giger (1993), reported a log K_{ow} of 4.12. OP and its low mole ethoxylates are somewhat more water soluble than the corresponding NP and NPE. The log K_{ow}s for the OPE compounds are therefore slightly lower than the values of 5.28 for OP and 5.09 for OPE on which the bioaccumulation scores were based. (D20:9)

- For 4-NP, EPA's RM1 Document identifies measured BCFs of 271 to 344 in the fathead minnow based on studies conducted for CMA by EnviroSystems (1991). See RM1 Document at 12, 14. BCF studies in the fathead minnows also have been conducted by the EPA Duluth Laboratory. EPA Duluth reported a BCF of 740 for the fathead minnow and 220 for blue gill sunfish. Brooke (1993). In addition, MITI Japan reported BCFs of 220 in bluegill sunfish and 0.9 to 3.3 in carp. MITI (1992). In prioritizing BCF data sources, EPA indicates that "measured bioconcentration factors from fish are used preferentially to those obtained from invertebrates, and those from invertebrates are used preferentially over measured values from aquatic plants." User's Guide, Appendix B, at p. B-11. All three of these studies used vertebrates at test species and therefore are preferred in the data hierarchy. (D20:10-11)

- Log K_{ow} is a very poor predictor of bioaccumulation potential for compounds that are metabolized by aquatic organisms. This is demonstrated be field bioaccumulation data for APEs, including NPE, that demonstrate that aquatic organisms easily metabolize these compounds. See Staples et al. (1997); Ahel, et al. (1993b). Ahel et al. measured non-lipid-based, fresh weight field BAFs for fish of 6 to 15 for NP and 0.8 to 37 for NPE-1 and 2. Ahel et al. (1993b). In addition, in its littoral enclosure study, the EPA Duluth Laboratory measured a non-lipid-based, fresh weight field BAF of 87 for blue gill sunfish. See Liber et al. (1996). The EPA data are reported in the EPA's RM1 Document for 4-NP. See EPA, RM1 Document for Para-Nonylphenol (October 2, 1996) (hereinafter "RM1 Document) at 12, 14 (Table 12). (D20:7-8)

- 4,4'-MDI was assigned a bioaccumulation score of 3 based on a predicted octanol/water partition coefficient (log Kow) of 5.22 and a calculated bioconcentration factor (BCF) of 5,460, which was derived from the calculated log Kow. See WMPT Chemical Data Summaries. This log Kow value has no relevance to the actual potential of 4,4'-MDI to bioaccumulate. As discussed above, 4,4'-MDI has a very short half-life in the presence of water. In addition, isocyanates have a high degree of reactivity with other biological nucleophiles. Brown et al. (1987). Therefore, it is not possible for 4,4'-MDI to maintain its chemical identity and bioaccumulate in organisms. Moreover, a study of the fate and effects of polymeric MDI on a pond showed no detectable 4,4'-MDI in rainbow trout, and therefore no detectable potential for 4,4'-MDI to bioaccumulate. Heimbach et al. (1996). Thus, the bioaccumulation score for 4, 4'-MDI should be 1. (D19:6)

- In addition, Yakabe recently reported a log K_{ow} of 4.5 for 4,4'-MDI using High Performance Liquid Chromatography (HPLC) under conditions where the reactivity of the 4,4'-MDI was low enough that it survived the process. See Yakabe (1997). Yakabe also studied several other aryl isocyanate compounds to develop a Fujita-Harnch constant for the isocyanate group. These data further reflect the low potential for 4,4'-MDI to bioaccumulate and should be the preferred choice of reference values in the WMPT over the predicted log K_{ow} for 4,4'-MDI. (D19:6)

- The three TDI listings on the Draft Prioritized Chemicals List were assigned bioaccumulation scores of 2, based on a predicted log K_{ow} of 3.74 and a calculated BCF of 410 derived from the calculated log K_{ow} value. See

Chemical Data Summaries. The predicted log K_{ow} is not relevant to the actual potential for TDI to bioaccumulate. As discussed above, TDI has a very short half-life in the presence of water. In addition, TDI is highly reactive with other biological nucleophiles. Brown et al. (1987). Because it is not possible for TDI to maintain its chemical identity and bioaccumulate in an organism, the bioaccumulation score for TDI should be 1. The bioaccumulation score of 1 also is supported be the log K_{ow} value for TDI reported by Yakabe (1997). Yakabe recently reported a log K_{ow} for TDI of 3.4 using HPLC under conditions where the reactivity of TDI was low enough that it survived the process. Yakabe also studied several other aryl isocyanate compounds to develop a Fujita-Hansch constant for the isocyanate group. The WMPT data hierarchy should prefer these data to the predicted log K_{ow} for TDI. (D19:11-12)

- The bioaccumulation score for DBP is 2. The B is based on a Log P calculation of 4.72. However, the measured Bioconcentration Factor (BCF) for DBP in fish is 4, based on EPA's draft DBP Risk Assessment (March, 1997, report is attached and key data are highlighted). As we have commented above, we feel that experimental data should take precedence over estimations. For this reason, we suggest a score of 1 should replace the 2. (D32:10)

- DINP's bioaccumulation score in the draft WMPT is 3, based on modeled log K_{ow}s of 9.37 (CASRN 28553-12-0) and 9.52 (CASRN 68515-45-7). As discussed in Section III.D. the log K_{ow} is a poor predictor of phthalate bioaccumulation potential. The draft WMPT reports BCF values for DINP of 7,780,000 (CASRN 28553-12-0) and 10,100,000 (CASRN 68515-45-7). EPA has not provided a citation for these values, but they appear to be in error based on available measured data. Measured BCF data for DINP (CASRN 28553-12-0) include values of 183.8 in *Arca zebra* and 0.46 in *Diplora strigosa* (EU, 1997). These low values are in accordance with the general low bioaccumulation potential exhibited by phthalate esters, including data for the C8 and C10 phthalate esters that bracket DINP (C9) (Staples *et al*., 1997b). Therefore, DINP should be assigned a low bioaccumulation score. Under the draft WMPT methodology, its score should be 1. (D18:50-51)

- BBP's bioaccumulation score in the draft WMPT is 2, based on a modeled log K_{ow} of 4.91. As discussed in Section III.d., the log K_{ow} is a poor predictor of phthalate bioaccumulation potential. Measured data demonstrate that BBP has low potential for bioaccumulation (Staples *et al*., 1997a). BBP, like all phthalate esters, metabolizes quickly and completely. Carr *et al*. (1997) report a BCF of 12 for BBP. The work reported in Carr *et al*. Was the source information used by EPA in the GLWQI final rule which concluded that BBP is a non-BCC (GLI, 1995). Given the low measured BCF value for DEHA, under the draft WMPT methodology, the bioaccumulation score for BBP should be 1. (D18:69)

- [NOTE: this comment is paraphrased because a direct comment including the data was not provided.] The "Use and Exposure Profile for Isopropanol Revised Draft" (EPA, April 21, 997) provides a log K_{ow} of 0.05 (Hansch and Leo, 1995) and a BCF of 0.643 (SRC, 1997). In addition, the OECD SIDS IAR provides a log K_{ow} of 0.05 and a BCF of 1. (D16: Appendix IV, Appendix V)

- Rohm and Haas, using observed data instead of modeled data in estimating log K_{ow} for the Bioaccumulation score showed an OCS score of 15. In particular, the log K_{ow} was reported by Howard (1991) as 3.54 (which produces a Bioaccumulation score of 2), whereas WMPT used a value of 5.02 (which produces a Bioaccumulation score of 3) as estimated by CLOGP3.3. (D34: 5)

- The BCF for antimony has recently been revised from 1 (U.S. EPA 1980) to 0.5 (see page 6 in U.S. EPA May 12, 1989): "The BCF value of 1 determined by U.S. EPA (1980) was reevaluated in Stephan (1983). A new BCF of 0.5 was derived. Pertinent new information regarding the BCF value for antimony is currently undergoing Agency review. The BCF value of 0.5 (Stephan 1983) will be used until this evaluation has been completed." (D78, p. 12 of Appendix I)

- The WMPT model fails to recognize that log K_{ow} is a very poor predictor of bioaccumulation potential for chemicals such as pentachlorophenol that are readily metabolized and eliminated by aquatic biota. (D48:13)

- For example, EPA rejected measured bioaccumulation factors (BAFs) and measured bioconcentration factors (BCFs) and used a predicted bioaccumulation value based on a log K_{ow}. Additionally, EPA considers the modeled log K_{ow} to be high quality data," but the measured BCF to be "medium quality data." The measured data is much more preferable since they reflect actual biodegradation observed under actual site or test conditions, and incorporate metabolism processes that accurate reflect a chemical's actual bioaccumulation potential. Phthalate esters are classified by the WMPT as highly bioaccumulative. Yet measured data have indicated that a number of the phthalate esters are not bioaccumulative chemicals. Thus, this class of chemicals is inaccurately ranked. (D75:15-16)

- The log K_{ow} of pentachlorophenol is known to be highly dependent on pH and the pH dependence of the low K_{ow} values in the EPA reference is unknown. Across the range of environmentally relevant pHs for water bodies (i.e., pH 6-9) the log K_{ow} values for pentachlorophenol would range from 3.7 to 2.7. At near neutral pH (7.2), a value typical for many fresh water bodies, the reported log K_{ow} value is 3.32. The log K_{ow} value of 3.32 for pentachlorophenol has been used in other risk assessments on the chemical. Using a log K_{ow} of 3.32 (based on near neutral pH and the center of the typical environmental pH range), the score for the bioaccumulation parameter for pentachlorophenol would decrease from a value of 3 to a value of 1 using the fenceline values provided in the WMPT. (D48:14; D48:15)

- A lower score for the bioaccumulation potential should be used for pentachlorophenol. Using a pH adjusted log K_{ow} value of 3.32, the score should be reduced from 3 to 1. Alternatively if one uses BAF or BCF data to assign the bioaccumulation potential, a score of 2 would be appropriate. (D48:18)

- There is an apparent error in the derivation of the 7,868 BAF value used in the WMPT report. Even using the 12,000 value presumably obtained from Appendix B of the Hazardous Waste Identification Rule, we are unable to reconstruct the 7,868 value used in the WMPT. Our conclusion for the pentachlorophenol BAF is that there is no justification for the value of 7,868 or 12,589 in the cited sources. There is, however, considerable data supporting a significantly lower value, such as 600 to 650, for the pentachlorophenol BAF in cited sources. (D48:18)

- The bioaccumulation score for dicyclopentadiene is 2 based on the log P equal to 3.51. The Graphic Exposure Modeling System (CLOGP, EPA 1981) lists the log P as 2.89. We recommend changing the log P to 2.89, therefore changing the bioaccumulation score to 1. (D71:1)

- The bioaccumulation score for hexachlorocyclopentadiene is 3. This score is based on the log P equal to 5.05. The Hazardous Substances Database (published by Micromedex) lists the log P as 3.99. The bioaccumulation factor, which is based on the log P, should also decrease. We recommend changing the log P to 3.99, therefore changing the bioaccumulation score to 2. (D71:2)

- The Chlorobenzene Producers Association has submitted extensive information to EPA concerning several of the listed chlorobenzenes in connection with the Agency's 1996 consideration of a possible test rule for persistent, toxic and bioaccumulative materials under the Toxic Substances Control Act (TSCA). The information that the Chlorobenzene Producers Association provided to the Agency in that matter, including information about persistence, partitioning to the atmosphere, levels found in surface water, and toxicity levels in aquatic organisms is also relevant here. Appendices A, B, and C contain information relevant to 1,4-dichlorobenzene, 1,3-dichlorobenzene and 1,2,4-trichlorobenzene, respectively. (D68:7)

- Solvent Orange 7 has been assigned a bioaccumulation ranking of 3, most likely based on its log P value. It has been shown for colorants that log P is an inexact predictor of bioaccumulation because colorants either are too

hydrophilic, have too large a molecular size, or have a too low water solubility. Further, Solvent Orange 7 is negative in animal bioassays for carcinogenicity so should be assigned a lower toxicity ranking. (D41:2)

- WMPT relies on the logarithm of the n-octanol-water partition coefficient (Log K_{ow}) to determine bioaccumulation values. For some chemicals (e.g., PAHs), Log K_{ow} may overestimate actual bioaccumulation potential by not considering the likelihood that these substances may be readily metabolized by bacteria, plants, and higher organisms. Therefore, the impact on chemical scores would be to overstate, rather than understate, the risk associated with some chemicals. (E1:8,9)

- Ethylene glycol ethers and propylene glycol ethers are not bioaccumulative and should not be included among any list or ranking of PBT chemicals. (D45:2; D46:1)

- WMPT does not consider the mitigating influence of biotransformation that for some chemicals greatly reduces the bioconcentration factor. (D24:2)

- Bioaccumulation scoring must be modified to consider the transport of a chemical substance from one environmental media to another. (D49:2)

- The propensity of a substance to bioaccumulate must be considered concurrently with that chemical's toxicity. Some chemicals are so toxic that biological organisms are dead before the chemical has had a chance to bioaccumulate. Furthermore, when some chemicals bioaccumulate, their overall environmental risk is actually lessened. Bioaccumulation, like persistence, therefore, is not *always* bad, yet WMPT does not take such real-world considerations into account. (D54:2)

- A major flaw in the proposed procedure for assigning bioaccumulation scores is the assumption that K_{ow} provides a reliable predictor of bioaccumulation potential. Numerous studies indicate that K_{ow} is a poor predictor of bioaccumulation potential for industrial organic chemicals. This discrepancy is largely due to biotransformation by the exposed animal, which can significantly reduce the observed bioconcentration potential of a compound relative to simple K_{ow}-based predictions. In a comparison of predicted versus measured BCFs in fish (see Table 6 of comments), the predicted BCFs are generally consistent with the measured BCFs up to about a Log K_{ow} of 5. Above this value, significant departures between predicted and measured BCFs are observed. These observations are consistent with recent in-vitro metabolism studies with trout liver microsomes which indicate that the biotransformation rate of PAHs increases with Log K_{ow} (de Magaad et al., 1996). In this study, 90% of the variation in PAH biotransformation rates were explained by hydrophobicity. These authors hypothesized that the positive relationship observed reflects the increased partitioning of PAHs to the hydrophobic active site of the enzymes responsible for biotransformation. The measured vs. predicted BCF fish study also indicated that differences can arise depending on whether the experimental BCF is based on an analytical method specific to the parent compound or is instead based on the analysis of a radiolabeled compound which would not distinguish between the parent compound and associated metabolites. (D29A:12)

- Log K_{ow} is a very poor predictor of bioaccumulation potential for compounds that are metabolized by aquatic organisms. This is demonstrated by field bioaccumulation data for alkylphenol ethoxylates (APEs), including nonylphenol ethoxylate (NPE), that demonstrate that aquatic organisms easily metabolize these compounds. These very low field BAF values, including those measured by EPA's own laboratory, are well below the WMPT low concern fenceline of 250. Using the BAF fencelines identified in the WMPT, nonylphenol (NP), 4-nonylphenol (4-NP) and nonylphenol ethoxylate (NPE) should receive bioaccumulation scores of 1. (D20:7-8)

- K_{ow} is not a good predictor of bioaccumulation for chemicals such as PAHs and pentachlorophenol that are readily metabolized and excreted by animals. Therefore, the preferential use of K_{ow} to evaluate bioaccumulation is inappropriate. Such an error in applying the available data could result in a final score difference of up to 4; going

from a score of 3 for bioaccumulation to a score of 1, and then doubled because bioaccumulation is double counted in the WMPT algorithm. (D29:8; D31:16)

- EPA inappropriately considers modeled log K_{ow} to be high quality data, and measured bioconcentration data to be only medium quality. (D27:22)

- If "certainty" values were assigned to P, B, and T scores to account for the quality of the data, BCF and BAF scores should be given higher "certainty" values than log K_{ow} because the first two use measured data, while log K_{ow} uses estimated data. BCF data should receive a "certainty" score of 5, BAF data a 4 and log K_{ow} data a 3. (S1i:9)

- In terms of bioaccumulation, some of the chemical and physical characteristics of the chemicals are not incorporated in WMPT because it uses log K_{ow} data in preference to BAFs and BCFs. Log K_{ow} data may indicate high bioaccumulation, when in fact, the chemical is metabolized rapidly. When the BAFs or BCFs are known, these values should be used in preference to the log K_{ow}s. (S1i:36)

- Some of the chemical and physical characteristics of the chemicals are not incorporated in the model because the log K_{ow} may indicate high bioaccumulation when, in fact, the chemical is metabolized rapidly. There are models that can estimate the rate of metabolism. In addition, there are data on this for many chemicals. The WMPT uses a log K_{ow} or a BAF in preference to a BCF. The log K_{ow}s are predicted from an equation. When the BAFs or BCFs are known, these values should be used in preference to the log K_{ow}s. One might want to give precedence to the log K_{ow}s for the national analysis, while a facility might want to give precedence to measured BAFs and BCFs when using the WMPT for waste minimization purposes. This might, however, result in a problem if a community questioned why EPA gives a chemical high priority based on its log K_{ow} while the facility might give it a lower priority based on measured BCFs or BAFs. EPA could explore the idea of indicating in the documentation or the software that the user could choose between using the log K_{ow} or BAF or BCF. There should be a mechanism within the model for using measured BCFs or BAFs in preference to log K_{ow}s. EPA could list the type of indicator organisms which would appropriately be used in each EPA region so that a facility could measure BAFs and BCFs to challenge log K_{ow} results. This might be a longer term fix to the model. (S1i:11)

- The use of log K_{ow} as a primary predictor of bioaccumulation is a concern because the correlations between log K_{ow} and BAFs/BCFs may vary for different chemical groups. (E1:7)

- Great emphasis seems to be placed on the use of persistence and bioaccumulation in WMPT, yet the data used to measure these factors appear to be very scattered and inconsistent. Although the data being used in the system may be the best quality data available, it appears to be very rough. (S1e:16)

- The risk score and rank that EPA has given 2,4,4'-trichloro-2'hydroxydiphenyl either (i.e., "risk" score of 14 out of 18, and rank 86 out of 800) is inaccurate. Based on a preliminary review, the extensive database on triclosan has determined that the overall, human and ecological "risk potential" score for triclosan should be lower that "14" for the following reasons: (1) Conjugated triclosan does not bioaccumulate but is easily excreted; (2)Humans can easily conjugate triclosan either as a glucuronide or a sulfate; (3) triclosan conjugates are excreted in the urine and to a lesser extent in the feces; (4) The half-life for triclosan in humans is 4-6 hours; (5) On repeated exposures of humans, triclosan conjugates reach an equilibrium level in the blood; (6) When repeated exposure is discontinued, triclosan concentration in the blood returns to background level or zero; (7) After more than 25 years of use worldwide, there is no evidence that free triclosan, as such, persists in the human body or bioaccumulates; and (8) Triclosan data clearly demonstrate that triclosan does not bioaccumulate in aquatic organisms (fish), or in mammals.(D13:3)

- One commenter states that the OCS for dicofol drops from 17 to 15 when the observed data rather than the modeled data is used in estimating log K_{ow} for the bioaccumulation score.

- EPA inappropriately relies only on the K_{ow} value as a surrogate for bioaccumulation potential. (D36:5)

- There are several technical deficiencies associated with bioaccumulation estimates which severely limit their usefulness in the weighting process. (D37:i-ii)

- The bioaccumulation component needs to incorporate experimental lab and field data in order to account for limits in bioavailability in the natural environment. Environmental fate processes (e.g., biodegradability, hydrolysis, water solubility, volatility, and ionization) and organism physiology (i.e., processes of metabolism and elimination) are well known factors in attenuating observed rates of bioaccumulation versus model predictions based on octanol/water partition coefficients. (D37:iii)

- Because 4,4'-methylenediphenyl isocyanate (MDI) is highly reactive with water, the predicted log K_{ow} does not reflect the bioaccumulation potential of 4,4'-MDI. In water it is not possible for 4,4'-MDI to maintain its chemical identity and bioaccumulate in organisms. The high reactivity of 4,4'-MDI and other experimental data support a bioaccumulation score of 1. (D19:i,3,6)

- Because toluene diisocyanate (TDI) is highly reactive with water, the predicted log K_{ow} does not reflect TDI's low bioaccumulation potential. Available data, including a measured log K_{ow}, support a bioaccumulation score of I for TDI. (D19:ii,3,11-12)

- The WMPT should prefer measured log K_{ow} data to calculated values. The log K_{ow} predictive program (CLogP) is useful only when a measured log K_{ow} is unavailable. High quality measured data should always be preferred over predicted values. Measured log K_{ow} values are available for many compounds on the draft Prioritized Chemicals List. The measured log K_{ow} data indicate that 4-nonylphenol (4-NP), nonylphenol ethoxylate (NPE), octylphenol (OP) and octylphenol ethoxylate (OPE) have only slight to moderate bioaccumulation potential. These data support a bioaccumulation score of 1 based on the BAF data. (D20:8-9)

- The WMPT ignores high quality, measured bioaccumulation data that have been published in the peer reviewed literature or that have been developed or used by other EPA offices. In the case of 4-nonylphenol (4-NP), BCF measurements are available, using standard protocols and quality assurance procedures. These include data developed by EPA's own laboratories. The measured BCF values are all below the "high concern" BCF fenceline of 1,000 and demonstrate that these compounds are, at most, slightly to moderately bioaccumulative. (D20:i,3,10-11)

- The SAB has several comments with respect to the uncertainty within and validation of models predicting bioaccumulation and biomagnification, and recommends that additional field and laboratory data be collected to determine if such models can be used for other chemical classes. (EPA-SAB-EPEC/DWC-COM 95-COM 95-006 P.3). It is apparent, based on the inclusion of some color pigments in the WMPT analysis, which do not bioaccumulate, that EPA has not sufficiently verified the accuracy of what is a very simplistic model in the WMPT algorithm. Additional recommendations made by the SAB follow up on this point. Only robust extant field data of acceptable quality, i.e., data elements with acceptable precision, as defined by the Agency, should be used for model validation. If extant data are of unacceptable quality, then additional field data should be collected. Subsequently, the predicted biomagnification or bioaccumulation of pollutants should be compared to field measurements to assess the bias of the model. Until better approaches are developed for estimating water concentrations for compounds with log K_{ow} greater than about 6, decision makers must be aware of the increased scientific uncertainties associated with attempts to model super-hydrophobic compounds and especially wary of the use of the such results to support policy and regulatory decisions. Since the process of model development and

validation is iterative, MB/FW models used to predict bioaccumulation should be updated at regular intervals using the best current available empirical data (EPA-SAB-EPEC/DWC-CDM 95-006 P.4). Considerable analysis and verification work should have been undertaken prior to the publication of the WMPT. Organic color pigments are established super-hydrophobic compounds which are not bioaccumulative. As a result, the WMPT is almost certainly in error with respect to these compounds and should be amended or withdrawn. (D12:6-7)

- Organic and most inorganic color pigments do not bioaccumulate or bioconcentrate. As such, the proposed rule, which is intended to generate new reporting obligations for bioconcentrating toxics, should not be applied to organic pigments. Bioaccumulative substances are normally characterized by high persistence and toxicity, negligible metabolism, and a log P factor between 5 and 8. These substances may present a concern when widely dispersed in the environment. Therefore, when appropriate, the potential of a substance to bioaccumulate in the aquatic environment should be included as an exposure-related parameter in risk assessment. Biomagnification is not as widespread as commonly believed; it has only been demonstrated for a very limited number of substances. R. Anliker and P. Moser prepared a study published in Ecotoxicology and Environmental Safety (1987), Volume 13, P. 43-52, entitled "Bioaccumulation of Organic Pigments in Fish: Their Relation to the Partition Coefficient and the Solubility in Water and Octanol" (Attached). Anliker and Moser found that, although some of the pigments had calculated log P values within a range of concern, these pigments did not bioaccumulate in the aquatic environment. The authors concluded: that while the calculated P values of the investigated organic pigments were up to several order of magnitude above the critical value of 1,000, no accumulation in the fish as compared with the amount of pigments dispersed in the test-water was observed for the pigments tested. This inconsistency was attributed to the limited fat (lipid) storage potential of these pigments, indicated by their very low solubilities in n-octanol and their large molecular size. The authors also concluded that, as found by Opperhuizen et al. (1985), extremely hydrophobic chemicals with an effective cross section over 9.5 A, like the pigments tested, lack of uptake into biota (fish) can be expected as the membrane permeation seems practically impossible. Therefore, organic pigments were incorrectly incorporated into the initial lists of chemicals which are designated at bioaccumulators by EPA. The software must, at a minimum, allow the user to enter an actual octanol solubility in order to avoid the inappropriate assumption of bioaccumulation where none actually exists. (D12:10-11)

- EPA used modeled log K_{ow}, values over measured bioaccumulation factors (BAFs) and bioconcentration factors (BCF) and, indeed, over measured K_{ow}, values. Such an approach amounts to bad science, especially for the aryl phosphates, which have measured data that show the log K_{ow} to be a poor predictor of bioaccumulation potential. If it is important to rank a chemical for bioaccumulation, and no measured data are available, then the modeled log K_{ow} value might be used as a preliminary, conservative estimate of bioaccumulation potential, but there is no good reason to use modeled log K_{ow} values where valid measured data are available. EPA also justifies using modeled log K_{ow} values by claiming that they correlate well with BAF and BCF values. This is patently not true for the aryl phosphates. To improve the technical basis of the WMPT bioaccumulation scores, reliable measured BAF or BCF data should always be used preferentially over model predictions, particularly where inadequate documentation is provided to support use of the selected models. In the case of aryl phosphates, measured BCF data for cresyl diphenyl phosphate, tricresyl phosphate, and diethylpnitrophenyl phosphate show that these compounds should be assigned a bioaccumulation score of 1. (D21:i, 12-13)

- Although the oxo process chemicals properly received the lowest possible scores for persistence and bioaccumulation, information in the WMPT should be revised to incorporate actual persistence and bioaccumulation data, rather than including only modeled data. Particularly(D25:14)

- The source of data and methodology relied upon by EPA to determine bioaccumulation scores is unclear. For example, WMPT assigned a bioaccumulation score of 2 for trichlorophenylsilane based on log P values, even though it immediately hydrolyzes in water and would have not have sufficient time to bioaccumulate. (D49:2, 12-13)

- Log K_{ow} is used in preference to the BCF to determine bioaccumulation. Experimental measurements should be valued more highly than computer estimates. Bioconcentration studies can account for such factors as metabolism and lack of adsorption due to steric bulk that are not included in the extrapolation from the log K_{ow} to a BAF. The wide availability of log K_{ow} values does not make them higher quality data than data from rigorous experiments. (D32:3)

- Most P and B data are from models instead of from direct measurements, a relatively inaccurate way to evaluate P and B. Modeled P and B data, particularly the octanol-water partition coefficient, do not consider metabolism or photodegradation. (D32:4)

- The log P_{ow} estimation used to assign a bioaccumulation score is inconsistent with the experimental bioconcentration value. Experimental data should occupy a higher place in the data quality hierarchy than estimates. Therefore, TCP should be assigned a bioaccumulation score of 2, and dibutyl phthalate should receive a bioaccumulation score of 1, instead of 2. (D32:10)

- The WMPT's approach to bioaccumulation and bioconcentration data is mechanical and relies mostly on predicted/estimated values rather than measured data. (D27:13)

- In particular, scores are based on predictions from an n-octanol water partition coefficient (log K_{ow}). This does not account for metabolic factors and so represents a worst case measure of bioaccumulation. Measured values like BAFs and BCFs should be used preferentially. (D27:22, 79)

- EPA uses modeled K_{ow} values in the WMPT despite its own acknowledgment that other measurement data are preferable. Measured BAFs and BCFs are preferable to log K_{ow} values since they reflect actual bioaccumulation in an animal. (D27:22-24)

- The SAB has recommended that measured values be used instead of estimated values. (D27:23)

- EPA's rationale for using predicted log K_{ow} values in the WMPT (that they are more available than measured values and that the measured values tend to be specific to a particular site) do not justify ignoring measurement data when available. (D27:23)

- The BCF (e.g., from measurement values) is not site-specific (and is thus valid). (D27:23)

- The difference between measured and modeled bioaccumulation scores is illustrated by the different values for nonylphenol. WMPT relies on a modeled log K_{ow} value of 5.76, while OECD and EPA's Risk Management One document use the measured value of 4.48. This difference has resulted in a different final score for the WMPT. (D27:26-27)

- The WMPT uses inferior modeled predicted data for phthalate esters. Measured data should be used instead; a failure to do so is bad science. The justification that predicted log K_{ow} values should be used because they are more available is not valid. Also, EPA's assertion that bioaccumulation and bioconcentration factors tend to be more specific to a particular site is untrue, as is EPA's claim that modeled log K_{ow} values correlate will with measured bioaccumulation and bioconcentration factors. For these reasons, measurement data should be used preferentially over modeled data. Use of predicted over measured data has resulted in high scores for many phthalate esters where the measured data indicates low bioaccumulation. (D18:ia, 3, 41-42) In particular, bioaccumulation scores should be changed for the following phthalate esters:
  -Diiodecyl phthalate (DIDP), from 3 to 1. (D18:47)
  -Diisononyl phthalate (DINP), from 3 to 1. (D18:50-51)

-Di-n-octyl phthalate (DnOP), from 3 to 1. (D18:54-55)
-Di(2-ethylhexyl)phthalate (DEHP), from 3 to 1. (D18:61-62)
-Di-n-hexyl phthalate (DnHP), from 3 to 2 (with fencelines changed as previously recommended by this commenter). D18:63-64)
-Butyl benzyl phthalate (BBP), from 2 to 1. (D18:69)
-Dibutyl phthalate (DBP), from 2 to 1. (D18:74)
-Di-(2-ethylhexyl)adipate (DEHA), from 3 to 1. (D18:90)

- Commenter agrees with EPA's bioaccumulation ranking of 1 for Diallyl phthalate (DAP), Diethyl phthalate (DEP), Dimethyl phthalate (DMP), phthalic anhydride (PA); however, this value should be based on measured data rather than the modeled K_{ow}. (D18:76, 81, 82, 86)

- The use of modeled K_{ow} values to calculate bioaccumulation values has resulted in numerous scores of 3. Measured data for bioaccumulation and bioconcentration (cited in the literature) indicate that all commercially available phthalates have low bioaccumulation potential; the bioaccumulation score in the WMPT should be 1 for all phthalate esters. To be consistent with EPA's Great Lakes Water Quality Initiative, EPA should use only measured data in fish species. (D18:18, 40, 42-43, 44)

- EPA should explore the cost of being wrong in using modeling data versus testing data (i.e., using surrogate data in generating scores). (S1s:31)

- Regarding the use of predicted data in developing bioaccumulation and persistence scores, it seems that measured data may be more reliable. (E1:8)

- Model predictions may clearly contradict measured data, explaining why WMPT categorizes PAHs in a manner that is inconsistent with the Great Lakes Water Quality Initiative (GLWQI). For the Great Lakes, a detailed technical review was undertaken to assess available bioaccumulation data for numerous contaminants of concern. EPA scientists correctly concluded that PAHs should be deemed as non-bioaccumulative contaminants of concern. (D29A:13)

- To improve the technical basis of bioaccumulation scores, reliable measured BAF/BCF data should always be used in preference to model predictions. Information on specific isomers within a broad class should be used when appropriate for determining bioaccumulation scores. This approach recognizes that homologous chemicals with common structures will be metabolized similarly. (D29A:14)

- To be consistent with EPA's Great Lakes Water Quality Initiative and to better characterize indirect (i.e., food chain) exposure concerns, measured data should be restricted to fish species. (D29A:14)

c. Fenceline Values

- Bioaccumulation scoring of selected chemicals in the WMPT is not consistent with scoring of the same chemicals in the Great Lakes Initiative. These discrepancies demonstrate the errors resulting from EPA's failure to use measurement data. (D27:24-25)

- EPA does not make clear the rationale underlying the fenceline values it established, and this criticism also is made of the UCSS by the Science Advisory Board. For persistence and bioaccumulation, EPA set fencelines to give a 1:1:1 distribution (high, medium, low) for a sample set of chemicals. For toxicity (RfD data), the fencelines were set to give a 1:2:1 distribution. No explanation is given as to why these are the appropriate distributions, or why they differ for the toxicity factor vis-à-vis the persistence and bioaccumulation factors. (D20:6)

- The use of an upper-bound BCF/BAF cut-off value of 1,000 is too narrow to provide adequate discrimination across the range of BCFs for those chemicals being screened under WMPT. A particular BCF value is sometimes used as a criterion in chemical hazard evaluation, but the WMPT is based on a ranking scheme and not on a single BCF criterion or cut-off value. The chemicals being screened by WMPT have BCF/BAF values ranging across three orders of magnitude (1,000 to 100,000) as "high," while lumping less than one order of magnitude as "medium," and lumping the lowest orders of magnitude as "low." The BCF/BAF fencelines result in a narrow discrimination and appear very skewed in relation to those for log K_{ow} and for toxicity. (D29:7; D31:15)

- Except for those chemicals that undergo metabolism and are excreted, the BCF is generally considered to be correlated with the K_{ow}, which is presumably why both are listed as data elements for bioaccumulation scoring in WMPT. The proposed BCF/BAF fencelines do not follow the K_{ow} fencelines. A log K_{ow} = 3.5 (the low scoring fenceline) correlates to a BCF of ~ 1,000 (the high scoring fenceline); a low K_{ow} = 5 (the high scoring fenceline) correlates to a BCF ~ 30,000 (an order of magnitude above the high scoring fenceline). (D29:7,8; D31:16)

- EPA should change its low/moderate fenceline from 100 to 1,000 in order to provide better consistency between the WMPT and the Great Lakes Water Quality Initiative. A value of 10,000 should be used as the moderate/high fenceline value. (D27:79)

- The fenceline to differentiate low from moderate bioaccumulation potential should be raised to a value of 1,000 rather than the currently proposed 250. The moderate/high fenceline should be raised from 1,000 to 10,000. This shift would provide for a consistent assessment of bioaccumulation potential between the Great Lakes Water Quality Initiative and the WMPT. (D18:43-44)

- Regarding the fenceline values used to distinguish between high, medium, and low bioaccumulation values, it seems that there is a potential inconsistency between the high fenceline for the n-octanol-water partition coefficient (log K_{ow}) and the high fencelines for bioaccumulation factors (BAFs) and bioconcentration factors (BCFs). EPA should conduct a sensitivity analysis on fenceline values to ensure that chemicals are not inappropriately categorized as medium concern instead of high concern due to one or more misplaced fencelines. (E1:7,8)

- To better differentiate bioaccumulation potential between chemicals, the proposed fenceline must be widened. The current approach of assigning equal numbers of chemicals to low, medium, and high concern bins can seriously mischaracterized the relative bioaccumulation potential of specific chemicals. The fenceline to differentiate low from moderate bioaccumulation potential should be raised to 1,000. This would provide consistency in the bioaccumulation assessment between the Great Lakes Water Quality Initiative and WMPT. To distinguish chemicals with moderate/high bioaccumulation potential, a fenceline of 10,000 rather than 1,000 should be adopted. A strong weight-of-evidence argument based on field bioaccumulation data for representative PAH homologues can be provided for uniformly assigning all PAHs a low bioaccumulation score. (D29A:14, 15)

d. Other

- The scoring system used to evaluate bioaccumulation is flawed and fails to correctly to identify and characterize whole classes of compounds. These particular substances are not bioaccumulative even though the scoring process identifies them as such. (D12:3)

- EPA should research and evaluate the inclusion of measured bioaccumulation factors (i.e., from the AQUIRE database) developed by the EPA laboratory in Duluth, Minnesota to reduce the reliance on log K_{ow}. One recommendation in the meantime is that when log K_{ow} is used as a surrogate, selection should be based upon the protocol developed by the Agency K_{ow} workgroup. (E1:9)

- Chemicals with molecular weights greater than 600 and/or log K_{ow} values greater than 8 typically are viewed as having a low bioaccumulation potential; this should be incorporated by EPA into the scoring algorithm. (D27:79)

- In contrast to poorly metabolizable compounds, a comparison of BAF data from Stephan et al., 1993, to laboratory BCFs indicate that laboratory-derived BCFs significantly overestimate field BAFs. This discrepancy may be due to growth dilution and/or metabolic induction in field populations. (D29A:12, 13)

5. Human Toxicity Scoring

a. Data Quality Hierarchy

- Perhaps the most classic relative measures of toxicity, the oral LD_{50}, dermal LD_{50} and inhalation LC_{50} values, are not included in the WMPT. This omission, and the heavy reliance on the use of derived hazard values, seriously jeopardizes the credibility of this tool for use in waste minimization prioritization activities. (D76:4)

- Much of the data in the WMPT is already in derivative form; examples are reportable quantities, threshold planning quantities, and reference doses. Liberal use of derived hazard values such as these in this tool, which itself creates a derivative scoring method, promulgates a multiplicity of the errors inherent in the establishment of each. It is critical to realize that the derivative values mentioned above were developed for much different purposes than for waste minimization activities, making the use of reportable quantities, threshold planning quantities, and the like in the WMPT questionable, and perhaps entirely inappropriate. (D76:4)

- The toxicity data on individual chemicals ranked by the WMPT varies considerably in both quantity and quality. Other chemicals that have not had extensive testing, perhaps limited to a few acute toxicity studies in animals. By using the "best available" data for ranking a chemical by WMPT, EPA has created an arbitrary and systematic bias in the ranking of chemicals. For example, final chronic toxicity values when adjusted for EPA's highly conservative uncertainty factors are nearly always much higher than values based on acute toxicity data. Similarly, because EPA typically uses the highest PBT score when more than one data element is available, well tested chemicals will invariably score higher than the "data poor" chemicals. (Reference Chemical Manufacturer's Association/CCC comments, Subsection II C. 2. titled "The WMPT Penalizes Chemicals Having Well Defined Toxicity Profiles.") Pesticides are subject to extensive testing and thorough evaluation by EPA for health and environmental risks as required by FIFRA for registration. As described by the Chemical Manufacturer's Association comments above, it appears that pesticides are penalized by higher rankings from WMPT simply because of the greater availability of test data. (D69:6)

- There is no clear reason why extrapolated data should be determined to be of higher quality than the data from which it was derived. We propose that LOEL and NOEL values be considered high quality data and that they be used directly, instead of reference concentrations and reference doses. Consistent utilization of LOELs and NOELs would provide a more accurate comparison of the hazards of different chemicals, avoiding (unnecessary) introduction of significant uncertainty. It would also reduce or eliminate the need for the complex data weighting scheme built into the tool. (D64:3)

- A second problem with the WMPT system is exemplified by acrylic acid, which is scored 3 for human toxicity. The human toxicity score is based on an RfC of 0.001 mg/m^3, but the database also notes the RfD is 0.5 mg/kg/day. That RfD would merit a score of 1. Why the RfC value should predominate is nowhere explained. Such an arbitrary use of the highest possible score ignores the necessary consideration of likely routes of human exposure, as well as any reasoned assessment of the basis for the RfC and RfD values. (D63:3)

- The WMPT documentation fails to make the data used to compile the Priority List adequately transparent to a user of the Tool and Priority List. For instance, EPA ranks reportable quantities (RQs) and Threshold Planning Quantities (TPQs) established under CERCLA and EPCRA as "high quality" data sources for evaluation toxicity. Yet, most RQs and the TPQs have not been updated recently. (D30:10)

- EPA has not provided a sound explanation for its definitions of "low," "medium," and "high" toxicity categories or their corresponding rankings of 1, 2, or 3 and the application of these broad categories to large numbers of disparate chemicals. (D27:55)

- WMPT places greater emphasis on EPA peer review data than on the particular value of a given toxicity study and stresses that those data sources, such as the IRIS database, are high quality because they have undergone substantial internal EPA peer review. However, both IRIS and HEAST databases contain some toxicity values and information that are outdated and in need of revision, and none of the IRIS or HEAST values (i.e., Reference Dose (RfD), Reference Concentration (RfC)) are subject to peer review outside of EPA. EPA states that these databases are updated on a regular basis, but this is far different than a regular review and thorough analysis of the relevant data. This is particularly important as new concepts are developed (i.e., use of Physiologically-Based Pharmaco-Kinetic (PB-PK) modeling, epidemiological data, uncertainty factor revisions) for assessing human health risks. There is often additional information and data in the open scientific literature or in EPA databases under programs such as TSCA Section IV that possess equal or greater utility for assessing human health and ecological risks. The SAB had a number of recommendations for additional data sources that were not included in the WMPT (An SAB Report: Improving the Use Cluster Scoring System, August 1995, pp.5-7). (D32:1)

- Scoring for chronic human health effects should not be based on screening level or acute toxicity data, particularly when the "WMPT toxicity scoring approach emphasizes long-term or chronic toxicity" and when all of the other values in the human health toxicity portion of the WMPT are based on chronic toxicity. (D49:14)

- EPA should carefully examine the results presented in TSCA § 8 (e) notifications, rather than simply relegating such information to the "low" data quality category. Frequently, the protocols used to generate these data have been reviewed by panels of experts, and in numerous cases, have been subjected to in-depth quality assurance procedures. (D29:7)

- Aquatic RQs are not a reliable source for direct toxicity information; they are not updated regularly. (D27:33-34)

- The HEAST database is not "high" quality information; it consists of provisional risk assessment information. (D27:34)

- Using the lowest NOAEL or LOAEL as the basis for a human toxicity score without an evaluation of the quality of the study or method of dosing is indefensible. This policy is inconsistent with EPA's approach to deriving RfCs and RfDs, which requires considering the most relevant study. (For example, EPA revised the oral RfD for methyl ethyl ketone in 1993 based on recent data it received.) (D27:34-35)

- Non-comparable data sources are used to develop human toxicity scores. For example, TPQs are based on acute data whereas other toxicity measures in the WMPT are based on chronic data. (D27:45)

- An RfD or RfC is often more dependent on the number of uncertainty factors than on the effect or dose level seen in the relevant study, leading to incomparable results. For example, the RfDs for methyl ethyl ketone and acrylic acid are nearly identical but the derived NOAELs differ by about two orders of magnitude. Also, EPA has modified the way it uses uncertainty factors over the years. (D27:460)

- The WMPT scoring method for human toxicity penalizes well-tested chemicals through the use of derived values. Sufficient good-quality data exist for the phthalate esters to support the calculation of an artificially high derived toxicity value; a higher ranking may be obtained for these chemicals than for a chemical for which less testing has been done. Derived values should not be used. (D18:22)

- Another problem with the RQ is that both the RQ and WMPT rankings try to distill a variety of toxicity information into one number. Using the RQ in the WMPT ranking is redundant and could lead to inappropriate hazard classification. It would be more appropriate to remove the RQ from the ranking scheme. (D29A:6)

- The Human Health Structure Activity Team (SAT) Rank takes into consideration the potential carcinogenicity of a chemical, not just non-cancer hazards. However, WMPT uses the Human Health SAT Rank to determine the non-cancer ranking of a chemical. This is inappropriate since the SAT ranking considers non-cancer and cancer potential. This ranking should be removed from the non-cancer ranking. (D29A:6)

- The approach to using RQ for cancer data is also a problem in the WMPT rankings. The ranking scheme used for the RQ Potency Factor (RQPF) under WMPT is different than that used under CERCLA Section 102. The RQPF ranking scheme was originally devised under CERCLA Section 102, and therefore, the ranking scheme under WMPT should be the same. Under WMPT and CERCLA, chemicals are ranked into three potency groups; however, the numerical values used to define scoring bins for each group are more stringent under WMPT than under CERCLA. (D29A:6,7)

- Because RQs, a human toxicity data element, are based on data which are binned to generate RQ values, it seems that the underlying data (i.e., that which is binned) should be used directly. If an RQ bin is based on underlying data, there may be more potential for error if the underlying data are not used. The same is true of TPQs, which also are generating by binning based on underlying data. (S1e:17)

- With respect to human toxicity data elements and the data quality hierarchy, it does not seem appropriate to place the reportable quantities (RQs) and threshold planning quantities (TPQs) data elements in the same high data quality category as reference doses (RfD) and reference concentration (RfC). RQs and TPQs are normally grouped in very large, broad bins (e.g., 1, 10, 100). RQs and TPQs are bins themselves, therefore, to the extent that RQs and TPQs are used, WMPT is binning a bin. The impact these data have on the overall chemical scores should be examined. It seems that the underlying data should be used directly since RQs are based on underlying data. Since an RQ or TPQ bin is based on underlying data, there may be more potential for error if the underlying data are not used. (S1e:17)

- The various data elements applicable to a given subfactor are derived quite differently. For the human toxicity subfactor, RQs, cancer potency factors, Threshold Planning Quantities, and RQ cancer potency data elements are not equivalent, and therefore, should not be interchangeable within a data quality tier (e.g., with RfC and RfD data elements). Use of a continuous (possibly numeric) data quality scale with greater resolution should be considered. This would be similar to the current system which uses the highest quality data element, but would ensure that if both an RQ and an RfC are available, the RfC would be used even if it did not generate the higher overall score. With the current system, because RQs and RfCs are both considered high quality data, if both are available for a chemical and the RQ generates a higher score, the RQ value will be used over the RfC value even though the RfC is a higher data quality element. To resolve the issue of whether the human toxicity data elements truly are interchangeable, an analysis should be conducted with approximately 10 chemicals that have values for all human toxicity data elements to determine if the overall score changes more than one order of magnitude when different human toxicity data elements are used to generate the overall score. This would indicate if the human toxicity data elements are linked toxicologically and if they are indeed interchangeable. (S1s:30,31,33)

- Overlap between data used to determine non-cancer and cancer potential is another flaw with the WMPT ranking scheme. The main offender is the RQ, which is based on aquatic toxicity, acute mammalian toxicity, potential carcinogenicity, chronic mammalian toxicity, ignitability, and reactivity. Since the RQ is based on both non-cancer and cancer data, it does not specifically reflect the non-cancer potential of a chemical. Since cancer is typically a driver for characterizing the toxicity of PAHs, it is likely that the cancer potency would also drive the RQ. This would cause the non-cancer WMPT ranking to reflect the carcinogenic potential of the chemical, not its non-cancer potential. (D29A:5)

- The human toxicity scores are currently derived from several chemical ranking systems and listings, many of which are only indirectly related to inherent health hazard potential. Human toxicity scores can be based on actual

toxicity data, such as NOELS, LD_{50}s, and LOELs, but can also be assigned a score based on indirect measures, such as RQ, TPQ, or IRIS database values. Metrics such as NOELs and LOELs are more objective and represent actual toxicological values that should be used for WMPT toxicity rankings. RQ and TPQ are not indicative of actual toxicological characteristics, since they incorporate information that is not toxicity-based. As pointed out by the SAB, indirect data sources, such as RQ and TPQ, should not be used for the toxicity subfactor determination. Since indirect data sources are based on primary data sources, there is no reason to use the indirect data sources. (D32:1,2)

- The Agency's methodology sets broad priorities within the existing chemical program; it is not appropriate for ranking individual chemicals on a list that could be widely used and cited by the public as a source of information on a chemical's toxicity relative to other chemicals. The User's Guide states that where chemicals in the category have more than one ranking, the Agency will assign the more conservative (higher) number to the unranked chemical(s) in the category. Yet EPA itself has previously recognized that there is no meaningful way to generalize toxicity across classes of compounds because chemicals within a category often differ significantly in physical and chemical properties, and hence, in toxicity. For example, the human health scores for the aryl phosphates in the proposed WMPT are distributed fairly evenly across EPA's limited scale of 1 to 3. Thus, at best these Human Toxicity Ratings represent a broad approximation of the toxicity of an individual chemical. (D21:10-11;D25:12)

- Threshold Planning Quantities (TPQs) should be eliminated or moved to lower quality data categories because they do not provide high quality data pertaining to chronic health effects. For example, WMPT assigned an inaccurate human toxicity score of 2 to trichlorophenylsilane, which is based solely on a threshold planning quantity of 500 pounds. TPQ endpoints are intended to be screening tools for the purpose of emergency planning. This definition is completely inconsistent with the intent of other high quality data elements. In addition, TPQs (I) are based on short-term effects following acute-term exposures; (ii) incorporate acute lethality data; (iii) rely on the Registry of Toxic Effects of Chemical Substances, a non-peer reviewed data source, as the primary source of data; (iv) do not address key sources of uncertainty; and (v) are not peer reviewed (D49:3, 14-16)

- Reportable Quantity (RQ) values should be eliminated or moved to lower quality data categories because they do not provide high quality data pertaining to chronic health effects. While RQs are long-term effects criteria, these values are intended to be screening tools for the purpose of emergency response. In addition, RQs do not address key sources of uncertainty and are not peer reviewed. (D49:3, 17)

- The use of TSCA Section 8(e) submissions to rank chemicals should be eliminated. The WMPT User's Guide indicates that Section 8(e) submissions are ranked by EPA in an initial hazard screening as high-, medium-, and low-level of concern. These categories are interpreted in the same manner in the WMPT, with corresponding scoring of 3, 2, and 1, respectively. The 1-3 ranking was initially assigned for the limited purpose of document "triage" within the Compliance Audit Program's special circumstances and does not embody a risk judgement that should be applied under the WMPT. "Blind" use of the submitted Section 8(e) information and corresponding scoring in the WMPT to assign a human health score may be inappropriate because a submission may be associated solely with acute toxicity data, alter initial screening rank and are not readily available to stakeholders. (D49:23)

- The quality of the databases from which data can be used for a screening system varies significantly. Nonetheless, we disagree with EPA's selection of the priority given to different human toxicity data elements and the associated data quality hierarchy. Given that the purpose of toxicity values is to rank chemicals based on potential toxicity (not exposure), the toxicity component should predominate in the selection process. For example, the most sensitive chronic NOAEL or LOAEL should have precedence over either the RQ or TPQ, which are derived from toxicity and exposure-weighted schemes for use in other scenarios. Using RQs/TPQs and NOAELs/LOAELs in the same scoring system mixes apples and oranges. (D31:13,14)

- The TPQ is largely based on acute toxicity values (e.g., LC_{50} and LC_{LO} values), and should have less weight in a screening system based on minimizing the risk of chronic toxicity. (D31:13,14)

- The IRIS database was not created or designed to be used as a source of information for comparative risk evaluations, and it is inappropriate to place the highest priority on IRIS-derived values when assessing and prioritizing chemicals for their health risk potential to humans. IRIS values were designed to represent safe exposure levels for individual chemicals, but include policy elements that have nothing to do with the inherent toxicological properties of a given chemical. RfDs, RfCs, and cancer slope factors contain policy decisions such as the use of 10^{-6} risk as acceptable for carcinogens and the use of varying uncertainty factors when establishing safe exposure levels for non-carcinogens. These varying policy decisions in IRIS prevent the direct and objective comparison of chemicals with respect to toxicity potential. RfDs and RfCs also have very different endpoints and uncertainty factors for different chemicals. For example, chromium VI has a cancer endpoint while silver has a cosmetic endpoint, argyria. Silver has an uncertainty factor or 3 associated with its RfD, while chromium VI has an uncertainty factor of 500. Hence, the basic data and its quality must be evaluated instead of just using the final RfDs and RfCs, which are not directly comparable. (D32:2)

- Dibutyl phthalate has an RfD which is the fenceline between medium and low scores for human toxicity. WMPT should only be used as a first-tier screening tool for such chemicals because Dibutyl phthalate (DBP) has an uncertainly factor of 1,000 for its RfD. True comparison and ranking of chemicals based on toxicological properties would be more appropriately and objectively conducted if toxicological measures such as NOELs and LOELs were compared, rather than RfCs or RfDs. (D32:11)

- Given that the purpose of toxicity values is to rank chemicals based on potential toxicity (not exposure), the toxicity component should predominate in the selection process. For example, the most sensitive chronic NOAEL or LOAEL should have precedence over either the RQ or TPQ, which are derived from toxicity and exposure-weighted schemes for use in other scenarios. In addition, the toxicity elements are an uneven mix of cancer and non-cancer endpoints, and in addition to exposure information, are derived using physical characteristics, such as ignitability, which is clearly not driven by chronic health hazards. RQ data should be moved from the high data quality category and either eliminated as a data source or placed in the lowest quality data bin. Further, the TPQ is based on acute toxicity values, and should have less weight in a screening system based on minimizing the risk of chronic toxicity. (D29:6)

- EPA has chosen to parse data quality categories into three divisions (i.e., high, medium, and low), and then use the highest toxicity value within a given data quality hierarchy classification. An unfortunate consequence of this strategy is the apparently unintended penalization of "data rich chemicals" for which sufficient good quality data are available to support a valid estimation of toxicity. Comparing data rich chemicals with data poor chemicals is contrary to the tiered hazard assessment model in which the availability of more data serves to reduce (not increase) conservatism. The WMPT scoring system could discourage stakeholders from generating toxicity information on chemicals of interest. (D29:6)

- RfCs and RfDs and included in the WMPT as "high" quality data. However, these are established without considering severity, duration, or reversibility of an effect. (D27:13)

- The human toxicity database is inferior. Data derived from NOAELs and LOAELs receive higher quality ranking than the actual NOAELs and LOAELs from which they were derived. (D27:29)

- Using the higher of the non-cancer or cancer rankings to determine the toxicity potential of a chemical is inappropriate because this method does not take into account the relative quality of the data supporting cancer and non-cancer endpoints. It is possible that a high toxicity score which is derived from a low quality non-cancer data

point would be used to rank a chemical, rather than using ranks derived from higher quality cancer endpoint data which might show a lower toxicity score. (D29A:5)

- Non-cancer and cancer endpoints are very different in terms of how the toxicity is determined and how the chemicals are regulated. Choosing one endpoint over another does not fully represent the toxicity potential of a compound or give any information about what effects might be expected. It would be more appropriate to use the non-cancer and cancer rankings individually, or present some weighted average of the two values. Non-cancer and cancer data should be assessed separately and the results used separately in the final WMPT ranking. (D29A:5)

b. Data Sources and Accuracy

- In June of 1993, the Panel submitted data to the Agency showing that the RfD in the IRIS database should be revised to 0.25 mg/kg/day. The Panel also demonstrated why EPA should establish an RfC of 0.73 mg/m^3 that also would be included in IRIS. Since that time, however, EPA has published new guidance for deriving RfCs (EPA 1994). This guidance states that an uncertainty factor (UF) of 3 should be used for interspecies extrapolation if dosimetric adjustments have been made. Such dosimetric adjustments were made for MIBK, so the UF utilized by the Panel for interspecies extrapolation should be reduced from 10 to 3 to derive an RfC under EPA's current methodology. Accordingly, the RfC for MIBK should be 2.4 mg/m^3. (D17: 5)

- The WMPT uses the acetone RfD stated in IRIS to establish its score. Yet, as discussed in the comments separately submitted by CMA's Acetone Panel, EPA recently increased its RfD for acetone, choosing a drinking water study over the gavage study on which the previous RfD was based. In its decision granting a petition to delist acetone from the TRI EPA said: "EPA also acknowledges that the RfD has recently been revised. At the time of publication of the proposed rule, the RfD was 0.1 milligram per kilogram per day (mg/kg/day). EPA has revised this RfD to 0.9 mg/kg/day." (D27: 36)

- EPA has not identified elemental nickel as a human carcinogen, and the evidence clearly would not support such a classification. The only forms of nickel identified in the IRIS database as known or probable human carcinogens are nickel subsulfide and nickel refinery dust from pyrometallurgical sulfide nickel matte refining (both of which are classified by EPA as Group A Human Carcinogens) and nickel carbonyl (which is classified by EPA as a Group B2 Probable Human Carcinogen). As noted above, the ACGIH recently classified elemental nickel in category A5 -- signifying that it is "Not Suspected as a Human Carcinogen." See supra p.11. Furthermore, the International Agency for Research on Cancer ("IARC") has classified metallic nickel in category 2B, which equated to EPA's WOE category C. See User's Guide App. C at C-11. In these circumstances, we question whether elemental nickel should be assigned a cancer-based score, the score clearly should not be 3. As noted above, the WMPT equates an IARC classification of 2B with an EPA WOE classification of C. Under the WMPT Human Toxicity Scoring Fencelines for Cancer Effects, when a substance has a WOE=C, a score of 3 is assigned if the q_1* cancer potency slope factor for the substance is >10/mg/kg/day. See User's Guide App. C at C-6. If there is no cancer potency factor for the chemical, it is assigned a score of 2. See *id*. EPA has not established a cancer potency factor for elemental nickel (or even made the qualitative determination that it is a human carcinogen). Thus, if any cancer-based human toxicity score is assigned to elemental nickel under the WMPT, it presumably could be no higher than 2. The same would be true if a cancer potency factor for elemental nickel were "imported" from another nickel species. The closest thing EPA has to a cancer potency factor for elemental nickel is its cancer potency factor for nickel refinery dust, which is expressed as $2.4x10^{-4}$ $(\mu g/m^3)^{-1}$. That translates into a q_1* cancer potency slope factor of 0.84/mg/kg/day. Under the WMPT Human Toxicity Scoring Fencelines for Cancer Effects, a substance with a WOE=C and a q_1* cancer potency slope factor of 0.84/mg/kg/day is assigned a score of 2. Indeed, the same would be true if the substance had a WOE=A. (D56:12-14)

- Nickel's overall human toxicity score of 3 (high toxicity) apparently was based on cancer effects for which EPA derived a weight-of-evidence classification of A -- known human carcinogen. The WMPT does not contain any support for this designation, however, and it is inconsistent with the 1997 determination of the American Conference of Government Industrial Hygienists (ACGIH) that elemental nickel is "Not Suspected as a Human Carcinogen. It is also inconsistent with the 1990 finding of the International Agency for Research on Cancer (IARC) that nickel is a Class 2B, or possible human carcinogen. Under the scoring algorithm in the WMPT, nickel should receive at most a score of 2 for human toxicity based on the IARC classification. (D43:9-10)

- In June of 1993, the Panel submitted data to the Agency showing that the RfD in the IRIS database should be revised to 0.25 mg/kg/day. The Panel also demonstrated why EPA should establish an RfC of 0.73 mg/m^3 that also would be included in IRIS. Since that time, however, EPA has published new guidance for deriving RfCs (EPA 1994). This guidance states that an uncertainty factor (UF) of 3 should be used for interspecies extrapolation if dosimetric adjustments have been made. Such dosimetric adjustments were made for MIBK, so the UF utilized by the Panel for interspecies extrapolation should be reduced from 10 to 3 to derive an RfC under EPA's current methodology. Accordingly, the RfC for MIBK should be $2.4mg/m^3$. (D17:5)

- Based on informal feedback, the Panel understands that the IRIS RfC/RfD workgroup has reviewed the available MIBK data and has agree that the RfD should be revised upward, based on comments submitted by the Panel. The IRIS RfC/RfD workgroup also reportedly is considering establishing an inhalation reference concentration for MIBK, also based on comments submitted by the Panel. The timing of these revisions to IRIS in uncertain, however, because of current Agency resource constraints. Accordingly, in ranking MIBK for human health toxicity, EPA should not rely on the RfD and RfC currently in the HEAST database because the Agency will be revising those values. Indeed, use of the RfD from HEAST is particularly inappropriate because the Agency specifically withdrew that value from IRIS. Instead, the Agency should use the RfD and RfC proposed by the Panel, as they are based on more current scientific data and utilize EPA's standard methods for deriving RfD and RfC value. Use of this RfD and RfC results in a human health toxicity score of 1 for MIBK and a corresponding score of six on the draft PCL. (D17:5-6)

- EPA has published new guidance for deriving RfCs (EPA 1994). The new guidance states that an UF of 3 should be used for interspecies extrapolation if dosimetric adjustments have been made. In the case of MEK, such dosimetric adjustments were made, but an UF of 10 was used for interspecies extrapolation, as specified in the outdated RfC guidance, to derive current RfC. Using the correct UF of 3 for interspecies extrapolation reduces the total uncertainty factor from 3,000 to 900 (3 for interspecies extrapolation, 10 each for sensitive, and a modifying factor of 3), and produces a RfC value of $3.3mg/m^3$ (slightly greater than 1 ppm). Although it will not affect the overall human health toxicity score for MEK, the Panel believes the WMPT should be modified to reflect the appropriate RfC for MEK. As described above, because of EPA's promotion of the WMPT, the WMPT quickly could become a definitive source of toxicity data on individual chemicals. If the WMPT contains outdated or inaccurate information, that information will be widely disseminated to the public, creating a misleading impression of MEK's toxicity. EPA therefore has an obligation to ensure that the data in the WMPT is up-to-date and of high quality. (D17:9-10)

- A number of animal toxicity studies have been conducted on NP, NPE, OP and OPE. These included an oral 90-day subchronic study of 4-NP in rats, reporting a NOAEL of 50 mg/kg/day. Cunny *et al*. (1997). The SIDS Initial Assessment Profile of OP reports subchronic NOAELs of 15 to 30 mg/kg/day. SIDS Initial Assessment on OP (1994). In addition, Talmage reports several chronic studies of NPE and OPE, including chronic NOAELs of 140 and 200 mg/kg/day for NPE9 and NPE4 and a chronic NOAEL of 700 mg/kg/day for OPE40. See Talmage (1994). These studies demonstrate that NPE and OPE are of low toxicity, and should be used by EPA in scoring the human toxicity of these compounds. High quality measured data should always be preferred to predicted or estimated values. Although this approach is reflected in the User's Guide, EPA apparently took a different approach when implementing the WMPT. EPA's failure to use current information is extremely important

because EPA intends to widely disseminate the WMPT to the public. The Agency is widely promoting this tool for a variety of uses by regulators, environmental groups, industry and others. Therefore, the WMPT is intended to become a popular source for identifying the relative hazards of individual chemicals in the areas in which they are ranked. Even if the overall score is correct, where the WMPT contain inaccurate or outdated toxicity data, those data will be disseminated to the public and create a misleading impression of the available data and overall toxicity of chemicals. Accordingly, it is critical that the data underlying the rankings be accurate, transparent and up-to-date. (D20:16-17)

- Dibutyl phthalate's (DBP) human toxicity score in the WMPT is 2, based on a 0.1 mg/kg/day RfD and its 1,000 pound RQ value. As discussed in the comments separately submitted by CMA's Phthalate Esters Panel, the RfD values is based on a 1953 non-GLP study that shows a NOAEL of 125 mg/kg/day. This study, according to IRIS, used few animals of one sex only. IRIS additionally cautioned that "it was not indicated in the paper whether the 50% mortality observed early in the study was considered treatment-related, nor was the cause of death indicated. This is the only subchronic bioassay of dibutyl phthalate reported in the literature. Confidence in the study, data base, and RfD are all rated low. Yet, the National Toxicity Program (NTP) completed, in 1989, dietary subchronic studies in rats and mice that show NOAELs of approximately 350 mg/kg/day. If this more appropriate and up-to-date NOAEL derived from the NTP studies were used, DBP would receive a human toxicity score of 1. (D27:35-36)

- The WMPT has identified an RfC for methyl ethyl ketone (MEK) of 1.0 mg/m^3 as recorded in IRIS. The RfC was derived from a developmental toxicity study in the rat. To derive the RfC, EPA adjusted the NOAEL using total uncertainty factors of 3,000 (for intraspecies extrapolation, interspecies extrapolation, and modifying factors to reflect an incomplete database). Since this RfC was published, EPA has issued new guidance for deriving RfCs. Under the new guidance, an uncertainty factor of 3 (instead of 10) is used for interspecies extrapolation if dosimetric adjustments have been made. Since dosimetric adjustments have been made for MEK, the RfC should have been recalculated to reflect the actual inhalation risk presented by exposure to the chemical. Use of the correct uncertainty factors would derive an RfC of 3.3 mg/m^3. The comments separately submitted by CMA's Ketones Panel discuss in greater detail the deficiencies in the RfC value. (D27:37-38)

- CMA's and CCC's review of specific data elements also reveals that the sources identified for some chemicals do not, in fact, contain cite vales for those chemicals. For example, cresols' human toxicity score is derived from a 0.000001 mg/kg/day RfD. Although EPA stated that all RfD values were obtained either from IRIS or HEAST, neither IRIS or HEAST contains this RfD vale for cresols. The discrepancy in the cresols RfD is especially troubling because the RfDs recorded in the databases cited by EPA for m-cresol and o-cresol are identical -- 0.05 mg/kg/day, and p-cresol value was withdrawn by IRIS so that a new updated RfD summary could be prepared. (D27:52)

- Morgareidge *et al*. examined the incidence of tumor rates among rates exposed to beryllium in food at levels of 0, 5, 50 and 500 ppm. Like Schroeder and Mitchener, Morgareidge *et al*. found no differences in tumor rates between exposed and unexposed animals. Morgareidge *et al*.'s results for males are graphed in Figure A, and tests for statistical significance of differences in tumor rates among different exposure groups are given in Figure B. The corresponding graph and tests of significance for females are given in Figures C and D. Among the male rats, the incidence of tumors declined with increasing levels of beryllium after 5 ppm. Among females the pattern was not as consistent. Tumor rates among the 5 ppm group were higher than rates among the 50 and 500 ppm groups, but the 500 ppm group had slightly higher rates that the 50 ppm groups. In any event, none of these differences were statistically significant. Figure E is a calculation of a reference dose of .23 mg/kg/day for beryllium using the Morgareidge data. (D15:4-5)

- A given chemical may have conclusive data on the route of exposure that is of concern. For example, methylene chloride has been assigned a 2 rating for human toxicity based on its RfD of 0.06 mg/kg/day even though a RfC of

3 mg/m3 exists for methylene chloride. It is more reasonable and defensible to use permissible exposure limits (PEL) that are based on the expected route of exposure for methylene chloride, which is inhalation. The RfC would place it in the low (or 1) human toxicity category. Additionally, there is considerable epidemiological data indicating that methylene chloride creates no excess deaths from occupational exposures and is not a human carcinogen. These data should be considered in a weight-of-evidence approach suggested above. If only one piece of data is used, it should be the most appropriate data based on route of exposure, quality and relevance of the data. The worst case data should not be chosen a priori. (D32:6)

- The current RfD for DEHP, as described in the IRIS database, is based upon a LOAEL of 19 mg/kg for increased liver weight in female guinea pigs treated for one year (Carpenter et al., 1953). The Panel believes the selection of 19 mg/kg as a LOAEL is a misinterpretation of the study results. Contrary to the statement in IRIS, there were no differences in liver weights among groups. Furthermore, increased liver weights are associated with peroxisome proliferation, and more recent studies show that guinea pigs are not responsive to peroxisome proliferators (Mitchell et al., 1985; Osumi and Hashimoto, 1978), making an observation of increased liver weights in guinea pigs unlikely. (See the next Section (IV.D.1.b) and Appendix B for a more detailed discussion of this issue.) In actuality, female relative kidney weights, only, were significantly different from controls, and the authors stated, "This effect did not seem related to concentration" because the values were not dose-related. ATSDR has concluded that the LOAEL in the Carpenter et al. study, based on increased liver weight, actually was 52 mg/kg (ATSDR, 1993, p. 28). For renal and other effects in the guinea pig, ATSDR reports Carpenter et al. as providing a NOAEL of 52 mg/kg (Id.). (D18: 55-56)

- In any event, Carpenter et al. is not the most appropriate study for deriving the RfD because : 1) it is over 40 years old; 2) the observed effects were minimally adverse (As discussed in Section IV.F.1.a, elevated liver weights are not in themselves adverse effects, but may simply reflect a normal physiological response to prolonged feeding of large amounts of an organic chemical that must be metabolized and excreted.); and 3) more recent rodent studies provide information on chronic effects. The Panel believes a more appropriate study would be the developmental toxicity study conducted by Ty et al. (1988). The NOAEL in that study was 44 mg/kg based on skeletal anomalies in mice. Applying uncertainty factors of 10 for interspecies variability and 10 for intraspecies sensitivity, the RfD would be 0.44 mg/kg. (D18: 56)

- The draft WMPT assigns BBP a noncancer toxicity score of 1, based on an IRIS RfD of 0.2 mg/kg/day. The Panel agrees that BBP has low toxicity. If EPA retains the RfD values on the WMPT, however, it should revise the RfD for BBP. The chronic NOAEL and LOAEL for BBP are taken from the study that was used to derive the RfD (NTP, 1985), and they also should be revised. According to EPA, the NOAEL for BBP ion the 26-week NTP study was 159 mg/kg/day, based on the increased liver weights seen at 470 mg/kg/day. However, elevated liver weights are not in themselves adverse effects, but may simply reflect a normal physiological response to prolonged feeding of large amounts of an organic chemical which must be metabolized and excreted. Accordingly, both Hazelton, the laboratory conducting the study, and NTP, sponsor of the study, state that the no observed treatment-related effect level was 470 mg/kg/day (NTP, 1985b). An abstract reporting the results of the 26-week study did not cite the liver weight findings, and reported that toxicity was only seen at the highest does -- 2.5% or 2875 mg/kg (Rauckman et al., 1985). Moreover, although liver weight changes were observed at 470 mg/kg/day, these effects were not observed at the higher dose level of 2875 mg/kg/day. Because no liver weight changes were noted at the higher dose level, the biological significance of the changes at 470 mg/kg/day is questionable. Nor were any functional changes noted. (Histopathology was not accomplished, so that no comments as to morphological changes, the other possible justification for EPA's choice of a lower NOAEL, can be made.) Other subchronic and chronic studies support a NOAEL of 470 mg/kg/day. In light of the conclusions of the NTP (1985b) study director and sponsor and a subsequent review of the data, the NOAEL should be set a 470 mg/kg/day. Furthermore, the interspecies extrapolation factor should be reduced to 3.....Finally, no factor is necessary for subchronic to chronic extrapolation.....With these adjustments, the RfD for BBP on the WMPT

should be 12 mg/kg/day (470 mg/kg/day reduced by 3 for interspecies extrapolation and 10 for intraspecies sensitivity.) The chronic NOAEL should be 470 mg/kg. (D18: 64-66)

- The draft WMPT noncancer human toxicity score of 2 for DBP is based on an IRIS RfD of 0.1 mg/kg/day. As discussed in Section III.A.1., above, the Panel believes EPA should not rely on derived values, such as RfDs, for ranking chemicals in the WMPT. If EPA, however, retains RfD values on the WMPT, it should revise the RfD and the score for DBP. The RfD for DBP (0.1 mg/kg/day) is derived from a rat study yielding a NOAEL of 125 mg/L (Smith, 1953). To this, EPA applied an uncertainty factor of 1000, which includes a factor of 10 for interspecies extrapolation, 10 to extrapolate form subchronic to chronic, and 10 for intraspecies extrapolation. The effect observed in Smith (1953) was mortality within the first week of 50 percent of animals receiving the highest dose (600 mg/kg/day). The remaining animals survived the one-year study with no apparent ill effects. The IRIS database assigns a low confidence rating to the study and to the RfD because Smith (1953) used few animals of one sex only, it was not indicated in the paper whether the 50 percent mortality was considered treatment-related, and the cause of death was not indicated. Furthermore, the study is 44 years old and was not conducted in accordance with Good Laboratory Practices. The early mortality has not been replicated in subsequent studies. For example, there was 100 percent survival in rats fed 2,500 mg/kg/day of DBP bor thirteen weeks in a recent NTP study (NTP, 1995c). The Panel believes a better study for deriving the RfD is that recent NTP developmental study (NTP 1995c). In that, mice and rats were treated for 13 weeks with dietary dose levels of 1, 1250, 2500, 5000, 20000, or 40000 ppm. NTP identified NOAELs of 2500 ppm (353 mg/kg) for mice and 5000 ppm (356 mg/kg) for rats. The LOAELs were 812 mg/kg and 712 mg/kg, respectively. Using the 353 mg/kg NOAEL, with uncertainty factors of 10 for interspecies extrapolation and 10 for intraspecies variability, the RfD should be 0.3 mg/kg/day. (D18: 70-71)

- The draft WMPT assigns DEP a noncancer toxicity score of 1, based on an IRIS RfD of 0.8 mg/kg/day. The Panel agrees that DEP has low toxicity. If EPA retains RfD values on the WMPT, however, it should revise the RfD for DEP to reflect more recent data for that chemical. The chronic NOAEL and LOAEL for DEP are taken from the study that was used to derive the RfD (Brown et al., 1978), and they also should be revised. NTP (1995d) conducted a dermal carcinogenicity study on DEP. There was not evidence of a carcinogenic effect in rats and only equivocal evidence in mice following two years exposure to 0, 7.5, or 30 μL of DEP. NTP found "no evidence of chronic toxicity" even at the highest dermal dose of nearly 1500 mg/kg. NTP also has conducted developmental and reproductive studies of DEP (NTP 1988; 1985d). There were no developmental effects in rats following exposure to 1, 2500, 25000, and 50000 ppm dietary DEP and no fertility effects in mice form 0, 2500, 12500, or 25000 ppm dietary DEP. There was a decrease in sperm number at the 25000 ppm dose (4000 mg/kg).Using the NOAEL of 1800 mg/kg/day from the NTP reproductive study, and applying an uncertainty factor of 100 for inter- and intraspecies variability, the RfD would be 1.8 mg/kg/day. EPA should revise the WMPT accordingly. (D18: 77-78)

- The draft WMPT assigns DMP a human toxicity score of 1, based on a HEAST RfD of 10 mg/kg/day. The Panel agrees that DMP has low toxicity and should be assigned a low score. The draft WMPT value, however, was taken from the 1994 HEAST tables, which based the RfD on a 1955 report (Lehman, 1955). In the 1995 HEAST, EPA withdrew the RfD value, stating that it is not considered verifiable by the RfD/RfC Workgroup (EPA, Health Effects Summary Tables, FY-1995 Annual 13, 1-44 (EPA 540/R-95-036, 1995) [1995 HEAST]. There are, however, current studies on which to base chronic NOAEL and RfD values. For example, NTP reported a NOAEL of 50,000 ppm (3,600 mg/kg/day) in a feeding developmental study (NTP, 1989). Thus, the NOAEL is 3,600 mg/kg/day. Applying an uncertainty factor of 10 for interspecies extrapolation and intraspecies variability, the RfD is 36 mg/kg/day. EPA should revise the WMPT accordingly. (D18: 81-82)

- To avoid overstating the hazards of antimony trioxide, EPA should recognize that toxicity data fro the highly water soluble antimony potassium tartrate cannot and should not be used to assess the potential hazards from exposure to the far less water soluble antimony trioxide. Toward this end, EPA should make three significant revisions to the

WMPT and PCL. First, the WMPT data summary and PCL ranking for "antimony" should be limited to antimony potassium tartrate and other soluble forms of antimony, as the analysis is based on data generated for that compound. Second, the WMPT data summary for antimony trioxide (which did not receive a PCL ranking), should not include any data on antimony potassium tartrate, and in particular should not include the RfD for antimony potassium tartrate. (D78: 2)

- If permit limitations are not based on the dissolved fraction, U.S. EPA should consider establishing separate criteria for the less soluble and commercially more important antimony oxides. The available toxicity data from antimony trioxide, cited in the IRIS database, indicate a NOAEL of approximately 500 mg/kg/day (approximately three orders of magnitude above the LOAEL for potassium antimony tartrate, 0.35 mg/kg/day). (D78: Appendix I p. I)

- Why is the Cancer Data section not current? (For example, the NTP completed a TCP cancer bioassay and found TCP does not have carcinogenic activity). (D21: 6)

- A number of animal toxicity studies have been conducted on NP, NPE, OP and OPE. These included an oral 90-day subchronic study of 4-NP in rats, reporting a NOAEL of 50 mg/kg/day (Cunny *et al.*, 1997). (D20: 16)

- Differences in water solubility preclude extrapolation of test results for antimony potassium tartrate to antimony oxides. In particular, the RfD for antimony potassium tartrate should not be used for antimony trioxide. Also, in its analysis of antimony potassium tartrate, EPA should use total uncertainty factors of 200 to 500 (instead of 1,000) when deriving an oral RfD, to be consistent with the Agency's previous analysis of the key study. At the very least, an adjustment should be made to account for differences in water solubility. (D78:2,4-6,7)

- EPA's methodology may not be scientifically credible because it improperly generalizes toxicity across classes of compounds which may have widely differing physical and chemical properties. At best these rankings represent a broad approximation of the toxicity of an individual chemical. Although such an approach may have been acceptable in the Use Cluster Scoring System (UCSS), which sets broad priorities within the existing chemical program, it is not appropriate for ranking individual chemicals on a list that will be widely cited by the public as the definitive identification of a chemical's toxicity relative to other chemicals. (D17:ii,12-13)

- Several of the Chemical Manufacturers Association panels have done studies as required by the EPA to evaluate the hazard potential to humans and wildlife. These data are high quality and have been accepted and evaluated by EPA. For instance, the Chemical Manufacturer's Association Ketones Panel understands that the IRIS RfC/RfD workgroup has reviewed the available methyl isobutyl ketone data and has agreed that the RfD should be revised upward. Due to resource constraints, it is uncertain as to the timing of these revisions. So the older values were utilized by the WMPT, resulting in an inaccurate score for human health for methyl isobutyl ketone. Similar problems exist for a number of the phthalate esters. (D75:15)

- Under the WMPT's Human Toxicity Scoring Fencelines for Noncancer Effects, a substance is assigned a score of 3 if its Reference Dose (RfD) is <0.001 mg/kg/day. [See User's Guide App. C at C-5]. EPA has established an RfD for nickel based on a two-year feeding study of rats in which soluble nickel sulfate was added to the diet." The RfD is 0.02 mg Ni/kg/day." That RfD for soluble nickel salts cannot properly be attributed to elemental nickel, which would have a much higher RfD. But even if the inclusion of nickel in the Prioritized Chemical List is intended to encompass soluble nickel salts as well, an RfD of 0.02 mg/kg/day would result in a score of 2, not 3, under the WMPT's Human Toxicity Scoring Fencelines. [See User's Guide App.C at C-5]. The same is true if the Reportable Quantity (RQ) for nickel of 100 pounds is used. (D56:12)

- None of the possible problems with RfCs and RfDs is reflected in the WMPT. For some chemicals, no observed adverse effect levels (NOAELs) may be more meaningful to ranking toxicity than an unvalidated or outdated RfC

or RfD. Of course, if the RfC or RfD has recently been updated, it may be a valuable information source. The WMPT has no means of making the important qualitative determinations of what is in fact the best information. We doubt the Agency can devote sufficient resources to keep IRIS values up-to-date for more than a relatively few of the listed materials. Finding resources to make the other important scientific judgments needed is even more problematic. (D63:3)

- EPA assigned the highest quality rating to data derived from the Integrated Risk Information System (IRIS) database and the Health Effects Assessment Summary Tables (HEAST). The data that are currently available in this database and table were established years ago and are often based on outdated and/or flawed studies. (D75:14)

- The WMPT uses derived chronic toxicity values—RfDs, RfCs, threshold planning quantities (TPQs), cancer potency (q*), and reportable quantity potency factors (RQPFs)—to score chemicals for human toxicity. Secondary chronic values (SCVs) were used to estimate average concentrations of chemicals in water that cause unacceptable aquatic toxicity. EPA deemed these data elements as "high quality." Many of the "adjusted value" data elements (RfDs, RfCs, threshold planning quantities, etc.) are based on out-of-date studies. Additionally, the EPA published new guidance for deriving RfCs that was not incorporated into the database and therefore has not been utilized in the WMPT tool. This in itself could result in flawed scores and inaccurate rankings. (D75:14-15)

- The IRIS database, like many other databases, is incomplete and often unreliable. Frequently, it does not contain the most current and/or comprehensive review of the toxicological data that are available. EPA has acknowledged that the IRIS database contains flawed, erroneous data. And although the EPA has undertaken efforts to improve IRIS, the IRIS data are still not subject to external peer review. (D76:16)

- The noncancer effects score for dicylcopentadiene is 3. This score is based on the RfC which is defined as an EPA estimate of the highest inhaled air concentration the human population can be exposed to during a lifetime without deleterious effects. It is not explained how EPA derived the RfC. The other parameters score dicyclopentadiene as 1 or 2. We recommend a review of the RfC value. (D71:1)
- Human health data are missing/incomplete and, as always, the reference data is still subjective and not consistently derived. (D73:1)

- For the chemical CAS No. 5989-27-5, the scoring is different between the software and the hard copy. The software has a noncancer effects score tab, while the hard copy does not have a score for noncancer effects. (D74:1)

- As far as we can tell from the WMPT software, elemental nickel was assigned a Human Toxicity score of 3 on the basis of cancer effects apparently on the assumption that nickel has a weight of evidence ("WOE") classification of A (known human carcinogen) and no cancer potency factor. This cancer based score of 3 is neither scientifically justified, nor factually accurate, nor consistent with the WMPT methodology itself. (D56:12)

- The human toxicity databases and data used to score metals are outdated and inferior. Values were often established many years ago, and are based on outdated and/or flawed studies. Examples of erroneous, outdated, or suspect data for metals in the WMPT are provided for antimony, molybdenum, nickel, chromium, and vanadium. (D43:i,8-12)

- The Antimony Oxide Industry Association's principal concern is that the proposed WMPT overstates the hazards of antimony trioxide, which is used as a flame retardant in plastics, fabrics and other products, by using toxicity data for the highly water soluble antimony potassium tartrate to assess the potential hazards from exposure to the far less water soluble antimony trioxide. The Antimony Oxide Industry Association believes EPA should make two significant revisions to the WMPT and PCL. First, the WMPT data summary and PCL ranking for

"antimony" should be limited to antimony potassium tartrate, as the analysis is based on data generated for that compound. Second, the WMPT data summary for antimony trioxide (which did not receive a PCL ranking), should not include any data on antimony potassium tartrate, and in particular should not include the RfD for antimony potassium tartrate. (D66:2)

- Methyl methacrylate is scored as a 7, based on a human toxicity score of 2. The 2 is derived from a Reference Dose (RfD) of 0.08 mg/kg/day. Although that value had at one time been derived by EPA, the Agency has more recently as part of its IRIS Pilot Program reassessed the methyl methacrylate data and found that a more appropriate RfD is 0.7 mg/kg/day. Under the WMPT system, this higher RfD merits a human toxicity score of 1. This is but one example of the problem of outdated data in the software. For each of the many scored chemicals, new data become available regularly. Unless there is a means to incorporate that new data, there is a great likelihood the WMPT will be misused. (D62:2-3)

- It is not clear how the database was populated with available information. In looking through only two RCRA codes, K073 and F024, we found 15 instances where no data was entered for the Reportable Quantity when the compound indeed has a Reportable Quantity. The RQs are very obvious and easy to obtain, and yet there were significant omissions. What is the completeness of the database for other data sources that are not readily available to the public? Before the tool is rolled out in "final" form, it is essential to validate the completeness of the data entered into the system. (D64:3)

- The importance of discouraging further use of the WMPT is underscored by the questionable assumptions in some of its scoring methodology and the information errors in the database. Basic Acrylic Monomer Manufacturers, Inc. has not attempted to assess the full scope of the complex WMPT scoring and ranking system and all the assumptions upon which it is based. We note, however, two assumptions of dubious merit in the human health toxicity scoring methodology. First, the scoring hierarchy accepts RfCs and RfDs above all other values. That determination runs directly counter to EPA's recognition in a Memorandum it authored to settle Basic Acrylic Monomer Manufacturers v. Browner that IRIS may not contain the most recent, credible, and relevant information and that, in addition to IRIS data, all credible and relevant information should be considered (EPA Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, to all OAQPS personnel, Aug. 26, 1994). WMPT's prioritization of information sources ignores that many RfCs and RfDs have not been formally adopted in the IRIS system; others, although in the IRIS system, do not take into account any new data; and others are currently being revised consistent with a number of new Agency initiatives to improve the database (using, for example, PBPK and benchmark dose methodology). (D63:2,3)

- EPA based its human health toxicity score for methyl isobutyl ketone on the outdated values in the HEAST tables, even though the RfD in the HEAST table previously had been withdrawn from IRIS. EPA instead should rank methyl isobutyl ketone for human health toxicity based on the revised RfD identified by the RfD/RfC workgroup. Use of this RfD and RfC results in a human health toxicity score of 1 for methyl isobutyl ketone and a corresponding score of six on the draft PCL. (D17:i,4-6)

- Although EPA properly ranked isophorone for human health toxicity, the WMPT should not list isophorone as a carcinogen. The available evidence does not support a Group C carcinogenicity classification for isophorone (evidence cited in comment). The isophorone cancer slope factor should be removed from the WMPT to prevent misuse of this information. This is consistent with the chronic minimal risk level determined by ATSDR. (D17:i,6-8)

- The RfC identified for methyl ethyl ketone should be increased by a factor of 3 to reflect the 1994 revisions to EPA's RfC guidelines. Because of EPA's promotion of the WMPT, the WMPT quickly could become a definitive source of toxicity data on individual chemicals. If the WMPT contains outdated or inaccurate information, that information will be widely disseminated to the public, creating a misleading impression of methyl ethyl ketone's

toxicity. EPA therefore has an obligation to ensure that the data in the WMPT is up-to-date and of high quality. The SAB cautioned against using adjusted data such as RfDs and RfCs in the Use Cluster Scoring System, rather than raw data, because EPA's use of uncertainty factors has changed over time. (D17:i,9-10)

- Inadequate information is provided to permit meaningful review of, and comments on, the "human toxicity rankings." For example, EPA has not provided adequate information to determine the categories to which particular chemicals were assigned or the basis for the score assigned to the individual categories. Thus, the commenter was not able to provide in-depth comments on the human toxicity rating assigned to nonylphenol (NP) or nonylphenol ethoxylate (NPE). (D20:14)

- Clearly, selection of data from a peer-reviewed source such as IRIS, from which reference dose and reference concentration values are chosen, should have precedence over sources subjected to less scrutiny. (D29:6)

- Give highest priority to actual toxicological data, rather than IRIS values and FCVs. IRIS data and FCVs introduce various policy decisions, including various safety factors, so data are less comparable than actual experimental data. The quality and relevance of the particular studies and whether they have been externally peer reviewed are keys to determining the data quality for a particular chemical. (D32:cover1)

- As EPA agreed in the settlement of Basic Acrylic Monomer Manufacturing v. Browner (No. 93-1179, D.C. Circuit, March 9, 1994), "There may be more recent, credible, and relevant information available than is contained in IRIS . . . EPA or any state agency that uses IRIS should not rely exclusively on IRIS values but should consider all credible and relevant information that is submitted to the Agency . . ." EPA should heed its own warning and not consider IRIS the preferred source of data. If the Agency continues to use RfDs and RfCs from IRIS as the preferred data sources, the associated NOAELs or NOELs should be used instead of the actual RfD or RfC to eliminate the subjective uncertainty and safety factors that are not representative of inherent toxicity. (D32:2,3)

- With any data quality ranking system, judgement is necessary to determine which data are highest quality and most relevant to the route of exposure. Some data entries in IRIS note that there is low confidence in the source. Therefore, the rules on choice of data should have flexibility when a strong case can be made for different data choice priorities for a given chemical. External peer review and significance to the potential exposure pathway are other factors that should be considered when determining which data are highest quality for a given chemical. (D32:3)

- The WMPT should base the human toxicity scores on available animal studies rather than predicted, estimated or "prescored" values. Although EPA recognized that the human toxicity ratings for nonylphenol (NP), nonylphenol ethoxylate (NPE), octylphenol (OP) and octylphenol ethoxylate (OPE) based on chemical categories or SAR are "low," EPA apparently did not rely on the available chronic, subchronic and acute toxicity studies in evaluating the potential toxicity of NP, NPE, OP and OPE. EPA should use the available data to assess the potential health effects of these compounds. Even if the overall score is correct, where the WMPT contains inaccurate or outdated toxicity data, those data will be disseminated to the public and create a misleading impression of the available data and overall toxicity of chemicals. (D20:ii,3,16-17)

- The risk score and rank that EPA has given 2,4,4'-trichloro-2'hydroxydiphenyl either (i.e., risk score of 14 out of 18, and rank 86 out of 800) is inaccurate. Based on a preliminary review, the extensive database on triclosan, the overall, human and ecological "risk potential" score for triclosan should be lower that 14 since the chemical is regarded safe for humans for intended uses. (D13:4)

- The Reference Dose (RfD) of 0.08 mg/kg/day was used for the human toxicity scoring for methyl methacrylate (MMA). Yet, more recently the IRIS database was reassessed for MMA and a more appropriate RfD of 0.7

mg/kg/day was established. If used in the WMPT, the proper human toxicity score would have been lowered from 2 to 1. (D34:5)

- Basic Green 4 is assigned a human toxicity ranking of 2 and ecological toxicity ranking of 3. These rankings are not supported, however, by the scientific literature in which only a single, positive mutagenicity result test result, in *E. coli*, was reported, whereas no positive test results in carcinogenicity bioassays were reported. An ecological toxicity ranking of 3 does not seem justified since the relationship of the effects seen to those that would occur in the natural environment is unknown. (D41:2)

- Although many oxo process chemicals properly received the lowest possible score for human health toxicity, in ranking these chemicals the Agency improperly relied on outdated or nontransparent data sources and failed to utilize the most recent and most relevant information. (D25:3)

- Tools such as the WMPT and the draft PCL will only be as good as the underlying assumptions and chemical-specific data on which the Agency relies. It is critical that the most accurate and reliable health hazard information be used. Accordingly, if EPA is going to rely on the IRIS database as a starting point for the WMPT, or any other Agency initiative, EPA must commit the necessary resources to maintain a current database. (D25:14-15)

- EPA based its human health toxicity score for butanol on an outdated study in the IRIS database. (D25:i)

- The Reference Dose (RfD) of 0.08 mg/kg/day was used for the human toxicity scoring for methyl methacrylate (MMA). Yet, more recently the IRIS database was reassessed for MMA and a more appropriate RfD of 0.7 mg/kg/day was established. If used in the WMPT, the proper human toxicity score would have been lowered from 2 to 1. Also, the human toxicity score was based upon structure-activity relationships even though ample toxicity data has been submitted to EPA on the chronic and subchronic toxicity to mammals. Nevertheless, the human toxicity ranking using structure-activity relationships would not have been changed by the use of measured toxicity data for this chemical. (D34:5)

- For the OCS for 2-n-octyl-4-isothiazolin-3-one, a biocide, EPA used modeled data in estimating the human toxicity score instead of available observed data. In particular, for human toxicity, WMPT used the Chemical Class Human Toxicity Estimate, a structure-activity relationship yielding a human toxicity score of 3. Using a rodent sub-chronic NOEL = 20 mg/kg would yield a human toxicity of 2. (D34:5)

- Ethylene glycol butyl ether (EGBE) should have a human toxicity score of 1 instead of 2. The 2 is based on an RfC of 0.02 mg/m^3. Actually, there is no confirmed IRIS RfC for EGBE. The 0.02 value was a preliminary number generated by the Agency many years ago, never validated as an IRIS value, and should not receive preference as a peer reviewed value over the NOAEL. Use of the NOAEL (120 mg/kg/day) yields a human toxicity score of 1. More importantly, over the past two years a panel of scientists has been developing (for the first time) a peer reviewed IRIS RfC for EGBE, and the range of values under consideration are all well above 0.2 mg/m^3, which would also result in a score of 1. (D45:3)

- Diethylene glycol butyl ether (DGBE) should have a human toxicity score of 1 instead of 2 for the same reasons mentioned in the previous bullet (DGBE's score is based on EGBE's data). Also, the NOAEL for DGBE (18 mg/kg/day) results in a score of 1 for human toxicity. (D45:3)

- The human toxicity score for 4,4'-Methylenediphenyl isocyanate (MDI) should not be based on the Integrated Risk Information System (IRIS) Reference Concentration (RfC) which currently is under review by EPA. High quality chronic toxicity data not found in the WMPT database (e.g., 5000 lb. RQ, NOAEL and LOAEL data) support a human toxicity score of 2 for 4,4'-MDI. (D19:i,3,8-9)

- The human toxicity score for toluene diisocyanate (TDI) should not be based on the RfC, but should take into account available occupational epidemiology and animal toxicity studies. These data support a human toxicity score of 2. (D19:ii,3,13-14)

- The human toxicity scores rely on contractor reports and scoring models and methodologies that are not readily available for public review and comment. EPA and the WMPT have not provided adequate or accessible information to permit meaningful public comment on these parameters. (D20:i,3)

- The basis for the human health SAT ranks cannot be determined using the information provided by EPA. The commenter had no general objection to the use of SAR to estimate the toxicity of chemicals for which data are unavailable. However, where EPA proposes to make a tool available to the public that ranks individual chemicals based on SAR or SAR-like methodologies, the basis for those individual chemical rankings must be made available as well so that interested persons can assess the validity of the analysis, and, as appropriate, identify why modifications to the ranking should be made. (D20:15-16)

- On dilution of the WWTP effluent stream, the triclosan concentration at the intake of down stream drinking waterworks is below 0.1 ug/l. At these environmental exposure levels, there is no risk of injury to humans based on our toxicological data. (D13:5)

- Extensive safety data in both animals and humans have been developed on triclosan over a period of time extending almost 30 years and are currently filed with EPA (FIFRA Registration File 70404-2 and FDA (Drug Master File No. 916). The data in these files, to which very soon new data will be added, have also been reviewed and evaluated by an independent panel of experts who concluded that the database on triclosan is substantial and that the large margins of safety between levels of human exposure and levels found to be without adverse effects in long-term animal studies support both existing uses of triclosan and proposed new uses in oral health care products. Moreover, consumer products containing triclosan have been marketed in this country for almost 30 years and Ciba is unaware of any reports that would suggest that the product poses any risk of toxicity in humans. (D13:1)

- For beryllium and some beryllium compounds, the Chemical Data Summary in the software classifies beryllium and some beryllium compounds as carcinogens and assign them the highest possible cancer score of 3. EPA should reduce the cancer score for beryllium and compounds. A lower score is supported by the enclosed October 11, 1996 Draft Carcinogen Risk Assessment for Beryllium, which reviews the evidence on carcinogenicity for beryllium exposure. If EPA fails to reduce the cancer score for beryllium and beryllium compounds in their database, they will improperly be given the same score as the most potent carcinogenic substances. Their error will greatly mislead future users of the software as to the relative risk posed by beryllium and beryllium compounds. (D15:3)

- The noncancer score for beryllium nitrate is unexplained by the Chemical Data Summary. Since no data are listed for beryllium nitrate, other than the noncancer score, the score appears to be arbitrary and should be reduced. The noncancer score for beryllium chloride and beryllium fluoride are, ir anything, derived solely from their Reportable Quantities. As Reportable Quantities used were not based on noncancer effects, these scores are arbitrary and should be reduced. (D15:5)

- The American Zinc Association (AZA) was quite surprised to see that zinc was rated 2 out of a possible 3 for human toxicity, especially considering that: “EPA agrees that zinc is classified as an essential nutrient and, in terms of human health effects, the predominant concern cited in most of the available literature deals with the effects of zinc ion deficit rather than excess.” 60 Fed. Reg. 47334 (Sept. 12, 1995). As a result, AZA examined EPA’s methodology in deriving zinc’s score, and believes it has found several errors that explain the apparent inconsistency in the Agency’s view of zinc. (D50:3)

- Two data elements are given in the WMPT for human toxicity: the Reference Dose (RfD) and the CERCLA Reportable Quantity (RQ). Based on the fencelines listed for these two data elements, the RfD value of 0.3 mg/kg/day results in a human-toxicity score of 1, while the RQ value of 1,000 pounds results in a score of 2. EPA went with the more-conservative RQ value and assigned zinc's final score of 2" However, an extensive literature search shows that the RQ cannot be used as the basis for any human-toxicity score. (D50:3)

- The RQ for zinc was established in the *Technical Background Document to Support Rulemaking Pursuant to CERCLA Section 102—Volume 2* (Aug. 1986) (EPA Docket 102RQ) ("Tech. Doc."). See also 51 Fed. Reg. 34534, at 34537 (Sept. 29, 1986). An examination of the Tech. Doc. shows that the only data used for generating zinc's RQ of 1,000 pounds was toxicity data for aquatic and marine organisms no human health data were used. Tech. Doc., at 3-9, 3-19 n. 11. Basing a human-toxicity score on aquatic/marine toxicity that is contradicted by human RfD data is inappropriate and illogical, particularly when the RfD is more relevant to human toxicity. (D50:3-4)

- The Technical Document states that the RQ does not apply "if the diameter of the pieces of the solid metal released is equal to or exceeds 100 micrometers." Tech. Doc., at 2-8, 2-14. In essence, this means the RQ is only applicable to zinc dust. Therefore, the RQ value is inappropriate for use with zinc particles or massives which make up the overwhelming majority of zinc found in use commercially or in waste products. Since the RQ data are not appropriate for use in generating a human toxicity score, EPA should base the human toxicity score on the only other data element it has, the RfD, which yields a score of 1. Not only does this number have technical support, unlike the RQ, but it also squares with the Agency's correctly stated position that the health literature is concerned with zinc deficit, not excess. (D50:4)

- Zinc is not a typical waste constituent. As EPA knows, zinc is an essential nutrient for humans, animals and plants, and there is no substitute for it. Zinc is second only to iron as a trace metal naturally present in the human body. Zinc is the only metal found in all six classes of essential human enzymes. Among other things, humans need zinc for growth, immune system operation, reproductive development, and taste and smell. Zinc is involved in virtually all critical metabolic functions. The Recommended Dietary Allowance for zinc is 15 mg/day for adult males and 12 mg/day for adult females. Pregnant and lactating women require more—15 and 19 mg/day, respectively. For children under 11 years of age, 10 mg/day is recommended. (D50:7)

- Notwithstanding all of this, EPA developed a bright line concentration level for zinc on the basis of "verified human health effects data." 61 Fed. Reg. at 18792. However, EPA's statements accusing zinc of being a threat to human health are belied by its recent decision on a delisting petition under EPCRA: ..EPA agrees that zinc is classified as an essential nutrient and, in terms of human health effects, the predominant concern cited in most of the available literature deals with the effects of zinc ion deficit rather than excess..... 60 Fed. Reg. 47334, 47337 (Sept. 12, 1995). This strongly suggests that when EPA looks carefully and specifically at zinc, EPA concedes that zinc does not pose a significant threat to human health. This calls into serious question the human-health concerns advanced as justification for including zinc in the Rule. (D50:7-8)

- EPA's concession about the overarching problem of zinc deficiency squares with the conclusion reached in a recent extensive review of zinc and human health: "In summary, this review supports the consensus statement from the NAS/NRC report on Drinking Water and Health which stated that: In view of possible deficiency in U.S. diets, it is prudent to maintain all dietary sources of zinc .... The possibility of detrimental health effects arising from zinc consumed in food and drinking water is extremely remote..... There is no compelling evidence supporting a cause for concern about zinc in the environment as a putative toxic agent (Walsh, et al., "Zinc: Health Effects and Research Priorities for the 1990s", 102 *Environmental Health Perspectives*, June 1994 supp.)" In short, the Rule's claimed need to protect the public from zinc is unsupportable, and the Crosswalk must omit any reference to the Rule. (D50:8)

- EPA has used the RfD for zinc to help develop the bright line levels for zinc. 61 Fed. Reg. at 18854, draft §269.45. The RfD for zinc is 0.3 mg/kg/day. That RfD is simply too low. For a 7-kg infant, the RfD would only supply 42% of the U.S. RDA of 5 mg. For a 16-kg child (often used by EPA in modeling), the RfD would supply but 48% of the 10 mg U.S. RDA. For a, pregnant 40-kg woman, the RfD would furnish a scant 80% of the U.S. RDA. In other words, the RfD, if followed, would create the grave risk of zinc deficiency in the population. As seen above, EPA concedes that the literature on zinc is overwhelmingly concerned with deficiency rather than toxicity; however, the RfD promotes deficiency. (Note: American Zinc Association recognizes that EPA used the RfD to establish a level of "1" for human toxicity in the WMPT. Because the RfD is too low, this is an additional reason why the List's human toxicity score of "2" for zinc is insupportable) (D50:8)

- In August, 1995, EPA admitted to the American Zinc Association (AZA) that the zinc RfD is suspect: "The Agency realizes that the RfD methodology was not designed specifically to evaluate the essentiality and toxicity of essential trace elements (EM) such as zinc" (Letter from Jennifer Zavaleta, EPA, to George Vary, Executive Director of AZA, August 4,1995). Since that letter, AZA has been advised that EPA is reviewing the RfD methodology. Thus, AZA submits it is improper to establish bright line levels for zinc on the basis of an RfD that admittedly is flawed. (D50:8-9)

- Based on the RfD, EPA computed an MCL for zinc in drinking water at 2 mg/l in a June 1994 draft proposal on Phase VI-B under the SDWA. (Draft, phase VI-B Proposal, Office of Water, June 10, 1994). Recently, though, the FDA in its final rule on bottled drinking water established a maximum of 5 mg/l for zinc, a level equal to the current secondary MCL for zinc under the SDWA. And FDA even cautioned that level was one of several "aesthetically based allowable levels and do not relate to a health concern." (60 Fed. Reg. at 57125 (Nov. 13, 1995)). Thus, the RfD for zinc has been dramatically rejected by the FDA. This presents another reason why the exit level for zinc is erroneous, and a further Crosswalk cannot include zinc. (D50:9)

- Four of the aryl phosphates have been assigned human health scores of 2 or 3 based on either a "TSCA submission," a "Human Health SAT Ranking," or a "Human Toxicity Rating." The basis for these scores cannot be determined from the materials placed in the docket, such that interested parties are effectively denied a meaningful opportunity to comment. These human health scores, and overall chemical rankings derived from them, should be withdrawn unless and until the basis for these scores is fully disclosed and interested parties are given a fair and meaningful opportunity to comment. (D21:6-7)

- It is entirely inappropriate for EPA to rank the human health toxicity of chemicals when the basis for those rankings cannot be determined, evaluated or critiqued. For example, the WMPT identifies human health toxicity scores for three aryl phosphates based on a "TSCA Submission Score." According to the User's Guide, the TSCA Submission score was based on EPA's initial hazard screening (high, medium or low concern) of reports received under TSCA Section 8(e). The Agency claims that this information is publicly available through accessing the TRIAGE database, which can be obtained from an EPA Internet site. However, TRIAGE contains only extremely cursory information on reports submitted under TSCA Section 8(e). The database contains a "Tox Concern" heading, but this data element identifies only whether the Agency considers the test results to be of high, medium or low concern. No information is provided in the database on why the Agency determined that the results are of high, medium or low concern, although in some cases, the "comment" section identifies the study LOAEL or NOAEL, and, even more rarely, some explanation of the study results. The TRIAGE database simply cannot serve as a substitute for a reasoned explanation of how the Agency determined that these TSCA Section 8(e) submissions warrant a high, medium or low concern rating for individual chemicals. (D21:8-9; D25:10)

- No oxo process chemicals warrant a human health toxicity rating of 2 based on TSCA Section 8(e) submissions, but absent additional information in the record, to specific comments can be made on the Agency's analysis. (D25:10)

- EPA assigned a score of 2 to diethylpnitrophenyl phosphate, 2-EH, and a score of 1 to amyl acetate, butyraldehyde, butyl acetate, butanol, isobutyl acetate, ethyl acetate, isobutyric acid and propionaldehyde based on the "Human Health Structure Activity Team (SAT) Rank." No publicly available information exists to enable interested persons to evaluate the basis for this ranking. Documentation for the WMPT includes a general description of this methodology, but no information as to how it was applied to individual chemicals. There is not even a general explanation of what constitutes "evidence of an adverse human effect" sufficient to assign a "high concern" score under the SAT approach. Where EPA proposes to make a tool available to the public that ranks individual chemicals based on structure activity relationships (SAR) or SAR-like methodologies, the basis for those individual chemical rankings must be made available so that interested persons can assess the validity of the analysis, and, as appropriate, identify why modifications to the ranking should be made. (D21:9-10; D25:10-11)

- Ethyl hexyl acetate, butyl acetate, ethyl acetate, isobutyl alcohol, isopropyl acetate, propionic acid and propanol received a human health toxicity score of 1, and diethyl-p-nitrophenyl phosphate, amyl acetate, butyraldehyde, 2-EH, butanol, isobutyl acetate, isobutyric acid and propionaldehyde received a human health toxicity score of 2 based on EPA's "Human Toxicity Ranking." This chemical score apparently comes from classifications of chemicals into one of 150 categories that contain substances with similar chemical structures. EPA assigned a human toxicity rating to each of the 150 chemical categories based on available health hazard data for a limited number of chemicals assigned to that category. See User's Guide, Appendix C, at C9. According to the User's Guide, compounds received the human toxicity rating for the chemical category(ies) to which they were assigned. Unfortunately, EPA has not provided adequate information to determine the categories to which particular chemicals were assigned or the basis for the score assigned to the individual categories. (D21:10; D25:11)

- Butanol was assigned a human health toxicity score of 2 based on its current RfD of 0.1 mg/kg/day. Because the IRIS database is a non-statutory, in-house Agency activity, RfD values previously have not been presented for public review and comment, and therefore, EPA is asked to carefully consider these comments on butanol. EPA derived the oral RfD for 1-butanol from a 13-week study in which rats exposed to 500 mg/kg/day exhibited ataxia and hypoactivity. EPA identified a NOAEL of 125 mg/kg/day and applied UFs of 1,000 (10 for interspecies extrapolation, 10 to protect sensitive subpopulations, and 10 for extrapolation from subchronic to chronic) to derive a RfD of 0.1 mg/kg/day. The application of an uncertainty factor to extrapolate from subchronic to chronic, however, is not appropriate. The ataxia and hypoactivity observed in the 1-butanol study are properly characterized as short-term effects that occurred in response to very high bolus doses of the chemical. Such short-term suppression of the neurologic system is very different from a pathologic change or other long-term effects (e.g., histopathologic or hematological changes). Thus, this study supports characterization of 1-butanol as an anesthetic when administered at high bolus doses, but not as a neurotoxin. Moreover, 1-butanol is more rapidly oxidized in vivo by alcohol dehydrogenase than ethanol. Thus, humans are able to metabolize 1-butanol via normal metabolic pathways. An uncertainty factor is not needed to extrapolate from subchronic to chronic where, as here, the only effect seen in the subchronic study is better characterized as a transient acute effect. Furthermore, 1-butanol occurs naturally in fruits, dried beans, split peas, lentils, cheese, roasted filberts, and fried bacon. It is also used as a solvent in cosmetics (primarily nail preparations). Given the natural occurrence of this compound in foods, the accepted use of 1-butanol as a solvent in cosmetics, its metabolism by normal metabolic pathways, the general low toxicity of this compound, and the fact that the effects seen in the IRIS study are more properly characterized as transient, acute effects, no uncertainty factor is necessary for the extrapolation from subchronic to chronic. Thus, EPA should incorporate a human health benchmark for 1-butanol of 1.0 mg/kg/day in the WMPT. (D25:4-7)

- Human toxicity is based on EPA's Use Cluster Scoring System (UCS), which is not subject to verification. (D24:2)

- Silver was assigned a human toxicity score simply because of the existence of an RfD for silver, despite that this RfD is based on a cosmetic, not an adverse human health, effect. It appears that silver is the only known chemical contained in the IRIS database that possesses an RfD based solely on a cosmetic effect. There are no other known human health effects from chronic exposures to silver that warrant its inclusion on the WMPT list as a human health concern (i.e., as a score of 2 of human toxicity.). A detailed chemical-specific review should be conducted in order to identify additional factors and circumstances that might impact human toxicity. (D32:9)

- Vanadium is assigned a medium ranking for human toxicity based on an RfD. The endpoint of concern used to establish the RfD for vanadium is decreased hair cysteine in rats, an effect that has questionable toxicological relevance to humans. More extensive chemical-specific review should be conducted before assigning human toxicity scores based on RfDs. (D32:10)

- WMPT is based on data from the IRIS and HEAST databases, which include toxicity values that are outdated, incomplete, or not peer-reviewed—reducing the accuracy and reliability of the tool. (D54:3)

- Toxicity values such as RfDs, RfCs, TPQs, q*s, and RQ Potency Factors are based on LOAELs and NOAELs from long-term toxicology studies. LOAELs and NOAELs may be adjusted by a variety of factors. This can lead to WMPT toxicity scores that are inaccurate and arbitrary. (D27:19-21)

- Many of the adjusted value data elements (listed above) are based on out-of-date studies. Using these data elements for scoring and ranking chemicals is inappropriate and leads to arbitrary rankings. (D27:21)

- Derived values were often established many years ago and/or based on outdated and/or flawed studies. It is inappropriate to include studies from data for which good laboratory practices were not followed when better, more recent data exist. (D27:29-30; 46)

- Many of the processes for establishing the toxicity values that are used in calculating scores in the WMPT do not provide for any external peer review (e.g., the IRIS and HEAST databases). For example, the IRIS database is designed to be inclusive for available toxicity data, thereby containing a tremendous range in quality and age. Also, it does not include comprehensive data on many chemicals. It is therefore often unreliable; even EPA has admitted that IRIS contains incomplete information and should not have any binding regulatory effect. Public involvement in the creation of the database remains minimal. (D27:30-33)

- Numerous examples exist illustrating the dangers of using IRIS, HEAST, and other similar database values for WMPT purposes. The toxicity scores for dibutyl phthalate, acetone, p-cresol, ethylene glycol butyl ether, di-n-octyl phthalate, and methyl ethyl ketone are all based on inaccurate and/or outdated databases, leading to an incorrect toxicity score for the WMPT. (D27:35-38)

- For human toxicity scores, the WMPT ignores the advice of the SAB and uses incomparable and outdated data for phthalate esters. The extensive database that exists on phthalate esters is largely ignored. (D18:ia, 2-3, 19)

- Generally, the human toxicity data for phthalate esters indicate that they general are of low concern for human toxicity, yet many of the phthalate esters received a score of 2 in the WMPT. (D18:20-21)

- The WMPT scoring method for human toxicity utilizes noncomparable elements to score the phthalate esters. For example, EPA has used derived values like RfDs, reportable quantities, and threshold planning quantities that are all adjusted (and thus noncomparable) measures of toxicity. A better method (recommended by the SAB) would be to use only base parameters. (D18:21-22)

- Since the reportable quantities (RQs) for phthalate esters are based on outdated data, EPA should not include RQ values in the WMPT. (D18:23) Specifically, the RQ should be deleted for:
  -Di(2-ethylhexyl)phthalate (DEHP). (D18:56-57)
  -Dibutyl phthalate (DBP). (D18:71)
  -Diethyl phthalate (DEP). (D18:78)

- The WMPT should not include Human Toxicity SAT Rank, Human Toxicity Estimate, and/or TSCA submission values for phthalate esters. These values are of low quality and are not reviewable. Moreover, actual high-quality data exist for these values which should be used. (D18:23-26) Specific compounds which utilize some of these values include:
  -Di(2-ethylhexyl)phthalate (DEHP). (D18:57)
  -Butyl benzyl phthalate (BBP). (D18:67)
  -Dibutyl phthalate (DBP). (D18:71-72)
  -Diethyl phthalate (DEP). (D18:78)
  -Dimethyl phthalate (DMP). (D18:82)
  -phthalic anhydride (PA). (D18:84)
  -Di-(2-ethylhexyl)adipate (DEHA). (D18:86)

- Human toxicity scoring in the WMPT should reflect the available data, even for specific compounds that were scored correctly. Commenter is willing to provide copies of appropriate studies to EPA. Specific compounds for which this is true include (compounds were given a score of 1 in the WMPT):
  -Diiodecyl phthalate (DIDP) (D18:45-46)
  -Diisononyl phthalate (DINP) (D18:48-49)
  -Butyl benzyl phthalate (BBP) (D18:64-66)

- For Di-n-octyl phthalate (DnOP) in the WMPT, the RfD and the associated chronic LOAEL should be deleted because they come from an old Polish study that appears to have examined Di(2-ethylhexyl)phthalate (DEHP) rather than Di-n-octyl phthalate (DnOP). Based on other studies reviewed in the ATSDR Toxicological Profile for Di-n-octyl phthalate (DnOP), a chronic LOAEL of at least 1,000 mg/kg/day should be listed. Furthermore, the TPQ, Human Health SAT Rank, and the Human Toxicity Estimate values should be deleted for Di-n-octyl phthalate (DnOP). Overall, due to the low toxicity of Di-n-octyl phthalate (DnOP), a toxicity score of 1 should be listed in the WMPT. (D18:51-54)

- The RfD for Di(2-ethylhexyl)phthalate (DEHP) is based on an inappropriate study in the IRIS database. This study is over 40 years old, reported minimally adverse effects (elevated liver weights), and is overshadowed by more recent rodent studies with information on chronic effects. The RfD should be deleted or revised. (D18:55-56)

- The chronic LOAEL for Di(2-ethylhexyl)phthalate (DEHP) is incorrect and should be based on more recent studies. (D18:57)

- The WMPT assigns a cancer toxicity score of 2 to Butyl benzyl phthalate (BBP) based on data in the IRIS database. However, a conclusion on the potential for Butyl benzyl phthalate (BBP) to produce a carcinogenic response in rats cannot be made from the available data. No evidence of carcinogenic effect was observed for Butyl benzyl phthalate (BBP) in mice. In the rat, three separate studies conducted by NTP show different toxicological responses. There are no consistent findings of tumor types in these studies. Therefore, EPA should not score Butyl benzyl phthalate (BBP) as a carcinogen on the WMPT. Including such an entry in the WMPT will mislead the public about the toxicity of Butyl benzyl phthalate (BBP) and is indefensible in light of the inconsistent and irreproducible effects reported. (D18:67, Appendix C (1-6))

- The WMPT assigns a cancer toxicity score of 2 to Di(2-ethylhexyl)phthalate (DEHP) based on data in the IRIS database. However, the weight of evidence suggests that Di(2-ethylhexyl)phthalate (DEHP) should not be classified as a B2 carcinogen: rats and mice may be uniquely susceptible to Di(2-ethylhexyl)phthalate (DEHP) hepatic carcinogenesis, and there may be either no cancer risk or a threshold exposure level below which no oncogenic effect will occur in humans. Therefore, Di(2-ethylhexyl)phthalate (DEHP) should not be identified as a possible carcinogen in the WMPT. At a minimum, EPA should remove the cancer slope factor from the WMPT; the assumption that there is no safe dose for a carcinogen is almost certainly incorrect for non-genotoxic carcinogens such as Di(2-ethylhexyl)phthalate (DEHP). Thus, inclusion of the cancer slope factor in the WMPT will only provide misleading and inaccurate information to the public about the toxicity of Di(2-ethylhexyl)phthalate (DEHP). (D18:57-58, Appendix B(1-9))

- The overall toxicity score for Di(2-ethylhexyl)phthalate (DEHP) under the WMPT methodology should be revised to be 1. (D18:58)

- The RfD for Dibutyl phthalate (DBP) should be deleted or revised; it is based on an aged, flawed study, and a better study is available. (D18:70-71)

- The human toxicity score of Dibutyl phthalate (DBP) should be 1. (D18:72)

- The human toxicity score for Diallyl phthalate (DAP) should be revised to 1 according to current data; the CC Human Toxicity Estimate should be deleted. (D18:75)

- For Diethyl phthalate (DEP) and Dimethyl phthalate (DMP), the RfD and chronic NOAEL and LOAEL values should be revised to reflect more recent data. (D18:77-78, 81-82)

- For phthalic anhydride (PA), the RfC should be deleted or revised to reflect more recent data. Under the WMPT methodology, the human toxicity score should be 1. (D18:83-84, 85)

- EPA should not score Di-(2-ethylhexyl)adipate (DEHA) as a carcinogen. (D18:87)

- EPA has taken literally years to incorporate new data into IRIS, or to make scientifically appropriate revisions to RfCs and RfDs. If EPA continues to rely on the IRIS database, and other similar databases, it is imperative that the Agency commit the necessary resources to keep those databases current and technically sound. EPA has stated that it expects regulatory agencies and the public to use the WMPT to set waste minimization priorities and make risk management decisions. It is inappropriate for EPA to promote the use of databases such as IRIS and the WMPT for making risk management decisions and setting waste minimization priorities, however, when those databases contain outdated information that has not been subject to external peer review, particularly when more up-to-date information has been provided to the Agency (e.g., TSCA Section 4 data). EPA's consistent failure to utilize up-to-date information undermines regulatory programs that rely on Agency databases and results in inappropriate risk management decisions and misdirection of resources towards reducing the usage of chemicals which, in fact, do not pose hazards to human health and the environment. (D16:5)

- Silver (7440-22-4) is listed as possessing a Class 2 Toxicity. This is incorrect, silver should be listed as a Class 0 toxicity for the following reasons. In 1989, silver was dropped from EPA's 1991 Drinking Water Priority List because "there is either little or no potential for exposure via drinking water, or no adverse health effect associated with [its] presence in drinking water. Long-term exposure to silver is known to cause argyria, a grayish discoloration of the skin. Since this is considered a cosmetic effect and not a health effect, a secondary maximum contaminant level (SMCL) was proposed for silver (54 FR 22062, May 22, 1989). SMCLs are not federally enforceable and are established for contaminants in drinking water which may effect the aesthetic qualities and the public's acceptance of drinking water."

- Silver has been used for disease control since ancient times. The action of silver is purely chemical, not biochemical as is the case of organic antibiotics. The wide range in value of the silver salt of sulfadiazine is presented in ANTIBIOTICS, Vol. VI, Springer-Verlag, Heidelberg (1983), section on Silver Sulfadiazine. M.S. Wysor, author, presents the literature to show its effectiveness against bacteria, fungi, viruses, and protozoa. This silver compound, marketed by Marion Merrell Dow, Inc., as Silvadene, proved to be over 200 times more effective than sulfadiazine alone. It has become the most widely used antibacterial treatment for burns and indeed any type of open wound. No reports of toxicity despite the open wounds being treated have been reported. Additional epidemiological data accumulated over a period of centuries also supports this position. First, a 1% silver nitrate solution applied to newborns' eyes prevents blindness due to gonococcal ophthalmia. No toxicity to silver has ever been observed in this universally-used treatment. Second, silver amalgams were introduced for tooth restorations in 1830. A study by the US National Institutes of Health, Technology Assessment Conference Statement (dated August 28, 1991) on Effects and Side Effects of Dental Restorative Materials, states, "There no scientific evidence that currently used restorative materials cause significant side effects. Available data do not justify discontinuing the use of any currently available dental restorative materials or recommending their replacement." Third, the use of metallic silver to affect improved water purification filters began over 50 years ago, following extensive research by the Katadyn Products Ltd. of Switzerland. The Katadyn filter is sold worldwide and the US General Service Administration completed a contract agreement with Katadyn USA to allow any military or civilian agency of the US government to purchase directly, without the need for open bidding, any Katadyn filter listed in the company's catalogue. There are on the market today many other drinking water purification systems in which silver is a bacteriostatic that are approved by EPA. Fourth, silver/copper ionization swimming pool sanitation systems were introduced during the 1930s and are now universally used worldwide. As there is no patent protection for copper-silver ion systems, the industry, working with NSF International (formerly the National Sanitation Foundation), Ann Arbor, MI, has promulgated a national standard to certify silver-copper ion swimming pool sanitation systems. No evidence of human toxicity has surfaced. For additional information see "Growth Reported in Silver-based Systems for Swimming Pool Sanitization," *Backgrounder* issued by The Silver Institute on July 31, 1997. (enclosed)

- The exceptional effectiveness of electrically-driven silver ions for wound restoration of natural skin function following severe burns has long been a prime concern of military medicine. In severe cases, restoration often requires skin grafts, the success of which is not always assured. The importance of electrically-driven silver to nurture that success has now been established by extensive laboratory research conducted at the U.S. Army Institute for Surgical Research, Fort Sam Houston, TX. The Army Institute study employed silver-coated nylon fabric dressings, soaked in a saline solution placed over the burn wounds of laboratory rats. A small direct current of one tenth of a microampere (less than that normally used for human electrocardiograms) shortened the time for reconstruction of the skin faster than the same silver dressings without the electric current; the current accelerated the distribution of silver ions throughout the wound area. Also, with or without an applied current, silver-nylon dressings minimize inflammatory conditions in the wound area that result from uninhibited bacterial growth. For additional information, see "Silver's Importance to Health" *Backgrounder* issued by The Silver Institute on February 28, 1997. (enclosed) (D51:1,2,3)

- The WMPT software uses an outdated oral reference dose (RfD) for acetone from the IRIS database. The NTP concluded that the data from the studies were of limited relevance to likely human exposure scenarios. EPA's RfD/RfC workgroup concluded that the acetone RfD should be increased to 0.9 mg/kg/day, and the Agency reported the new RfD when it removed acetone from the TRI list. Use of the current RfD will result in a revised human health ranking for acetone of 1 (as opposed to 2), with a corresponding score on the draft PCL of 6 (as opposed to 7). (D14:i,3,4-5)

c. Consideration of Additional Sources of Human Toxicity Data

- The WMPT suffers from numerous technical defects that undermine the credibility and utility of the WMPT model and the PCL which it generated. Certain of the chemicals on the draft PCL, notably the pesticide chemicals, have been extensively tested in connection with registration requirements under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). Yet, the results of that testing are not reflected in the WMPT methodology which instead relies largely on modeling and other inexact estimation methods. (D48:3)

- Several peer-reviewed environmental, health and safety databases were entirely disregarded, such as those available through the National Library of Medicine (i.e., Hazardous Substances Data Bank). Also ignored were data sources compiled specifically to protect human health, such as Permissible Exposure Limit data from the Occupational Safety and Health Administration, the National Institute of Occupational Safety and Health's (NIOSH) Recommended Exposure Limit data, the American Council of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value data, the National Fire Protection Association hazard ranking system just to name a few. (D76:3)

- EPA has tentatively scored sodium dichloroisocyanurate as 2 - medium concern for chronic human health concern. This scoring was not based on any data, but on the opinion of the human health Structure Activity Team (SAT). This is considered low quality data, since it is based only on structure activity relationships (SAR), not experimental data. If NOAELs are available from well conducted animal studies, they are preferred over SAR predictions. The EPA Pesticides and Toxic Substances Division has recently conducted an extensive review of the many available animal studies (conducted for FIFRA registration purposes) available on the isocyanurates (sodium dichloroisocyanurate is one member of this group) in the final "EPA Re-registration Eligibility Document (RED), Chlorinated Isocyanurates", September 1992. It is clear from this review that the isocyanurates are not mutagenic and a 2-year bioassay for carcinogenicity was negative (no effect). The lowest compound related effect (in the absence of systemic toxicity where the maximum tolerated dose, or MTD, was exceeded) for chronic toxicity occurred in the male rat with a NOAEL of 154 mg/kg/day. This value is well above the 10 mg/kg/day "fenceline" value for a chronic NOAEL in the WMPT to classify the sodium dichloroisocyanurate family of chemicals as 1 - low human health toxicity concern. (D59:5-6)

- The one (of six categories) for which ethyl acrylate is not assigned a 1 is human toxicity. The assigned human toxicity score is 2, and the software indicates that score is based on Structure Activity Team Ranking and Chemical Use Cluster Human Toxicity Estimate Scoring of 2. We cannot determine how EPA obtained these scores. The WMPT User's Manual (at p. C-9) describes these two ranking schemes (both of which it notes are of "low quality") in general terms, but does not provide the data that the Agency used to score ethyl acrylate. The WMPT system favors human toxicity scoring based on what it terms "high" quality or "medium" quality information. For ethyl acrylate, a large toxicity database exists, and no observed adverse effect levels have been determined in both subchronic and chronic bioassays. Indeed, the available rodent chronic studies establish chronic NOELs that, according to the WMPT system, would merit a human toxicity score of 1. (D63:3,4)

- EPA has ignored the data previously generated on many ketones and provided to the Agency. Although many ketones properly received the lowest possible score for human health toxicity, in ranking these chemicals the Agency failed to utilize the most recent and most relevant information available about these chemicals. (D17:i,3-4)

- Extensive data exist on ketones and have been provided to EPA, yet these data are not reflected in the WMPT, which instead relies on outdated or modeled information. The commenter believes that EPA's consistent failure to utilize up-to-date information results in inappropriate risk management decisions and misdirection of resources towards reducing the usage of chemicals which in fact do not pose hazards to human health and the environment. In the end, tools such as the WMPT and the draft PCL will only be as good as the underlying assumptions and chemical specific data on which the Agency relies. (D17:ii,13-14)

- Much of the information regarding 3-idio-2-propynyl butyl carbamate (IPBC) in the prioritization software contradicts that provided in the Re-registration Eligibility Document on IPBC. Therefore, it appears that the Re-registration Eligibility Document on IPBC was not reviewed by EPA in developing the scores for IPBC in this software. The Re-registration Eligibility Document provides the most complete set of data assembled in a single location on IPBC and reflects the Agency's most recent analysis of those data. Therefore, EPA's waste minimization software analysis on IPBC should rely on the data in the Re-registration Eligibility Document. Because the software does not reflect this information, the Re-registration Eligibility Document should be utilized by the Agency to update the information provided in the software regarding IPBC. (D44:2)

- The software indicates human health risks for IPBC, 3-idio-2-propynyl butyl carbamate, which directly contradict EPA's most recent evaluation of IPBC as provided in the Re-registration Eligibility Document. The software assigns IPBC a score of "2" (medium risk) for human toxicity and persistence. However, the Re-registration Eligibility Document states that IPBC is not considered a developmental toxicant or mutagen, and is "not likely" to be a carcinogen. Moreover, the Re-registration Eligibility Document states that "IPBC is generally of low acute toxicity." Finally, the Re-registration Eligibility Document provides that a NOEL of <20 mg/kg/day was established for the 2 year chronic toxicity/carcinogenicity study. There is no basis, therefore, for a score higher than "1" for any human health risk category. (D44:4)

- For beryllium, the Chemical Data Summary assigns a noncancer score of 3. This score appears to be based largely, if not exclusively, on the Reference Dose and Chronic NOAEL. This reference does is based on a study in which laboratory animals were administered soluble salts of beryllium, not beryllium metal. Hence, this study should not be used on compute a Reference Dose, Chronic NOAEL or noncancer score for beryllium. In addition, the Reference Dose and Chronic NOAEL for beryllium are taken from the IRIS database for beryllium. As a preliminary matter, it should be noted that these values have been erroneously computed and should be increased substantially. The IRIS file for beryllium is and has been sadly out-of-date. For example, the IRIS file has not been revised to reflect EPA actions in 1992 to establish final drinking water standards and to withdraw the water quality criteria for beryllium. Recognizing the inadequacy of the IRIS file for beryllium, EPA has recently announced it is undertaking a revision of that file 64 Fed. Reg 14570 (April 2, 1996). As expressly noted in the IRIS database for beryllium, the Reference Dose and Chronic NOAEL are based on a study which administered beryllium sulfate to rats. Schroeder, H.A., and M. Mitchener. 1975. Life-term Studies in Rats: Effects of Aluminum, Barium, Beryllium and Tungsten. J. Nutr. 105: 421-427. Since the study related to the ingestion of beryllium sulfate, not beryllium, these data are relevant to a future Chemical Data Summary for beryllium sulfate, not beryllium. In any event, noncancer scores for beryllium should be reduced. (D15:3)

- Reference Dose and Chronic NOAEL calculated using the Schroeder and Mitchner study is too conservative. A NOAEL and a Reference Dose based on the studies of Morgareidge and his colleagues should be used rather than the NOAEL and Reference Dose which appears in IRIS. The studies of Kenneth Morareidge and his collaborators exposed animals to levels of beryllium sulfate that were considerably higher than that used by Schroeder and Mitchener. Details of Morareidge Study can be found in D15:4. (D15:4)

- Compared to Schroeder and Mitchener, Morgareidge et al. is a better choice for the determination of an NOAEL and Reference Dose because: (1) Beryllium was administered by the relevant route (oral), (2) Multiple dose levels were tested, (3) More complete histopathology was performed than in the Schroeder and Mitchener studies, (4) The data allow calculation of compound intake, rather than a guess, and (5) The study demonstrated no effects at two exposure levels which were higher than either of the other two chronic oral studies (Schroeder and Mitchener). (D15:5)

- A substantial body of data exists on the potential health and environmental effects of aryl phosphates, though much of the information appears not to have been used in the WMPT. (D21:3)

- Why is the cancer data section not current? For example, the NTP completed a TCP cancer bioassay and found TCP does not have carcinogenic activity. This information is not shown. (D21:6)

- Butanol should receive a score of one because its human health toxicity rank should be based on its inhalation effects, as the vast majority of butanol releases are to air. In 1995, more than 98 percent of butanol releases were to air. A recent thirteen-week inhalation study of butyl acetate (butyl acetate is rapidly metabolized to 1-butanol via normal metabolic pathways) examined subchronic toxicity endpoints, including histopathology of all major organs and tissues, as well as functional observation battery and motor activity tests. The no-observed-effect level (NOEL) was 500 ppm. Using EPA's Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry to calculate an RfC for butanol, the 500 ppm NOAEL was converted into mg/m^3, and dosimetrically adjusted to provide a human equivalent concentration (HEC) NOAEL, accounting for the noncontinuous duration of the dosing in the butyl acetate study. The $NOAEL_{HEC}$ is 424 mg/m^3. Applying an uncertainty factor of 10 to protect sensitive human subpopulations, three to extrapolate from animal data to humans (because EPA' s default dosimetric adjustments were used to derive a $NOAEL_{HEC}$ from the NOAEL) and three to extrapolate from subchronic to chronic results in an RfC of 4.2 mg/m^3. Using this RfC, which was calculated following EPA's methodology and is based on the highest quality available inhalation study, results in a human health toxicity score of 1 for butanol. (D25:7-8)

- The most recent data for dibutyl phthalate is from the report "Aquatic Toxicity of Eighteen Phthalate Esters" (Souter et al., Environmental Toxicology and Chemistry, Vol. 16, No. 5, pp. 875-891, 1997). These data should be incorporated in WMPT. (D32:11)

- The results for TSCA § 4 test rules should be included and accorded at least medium quality data designation. These toxicology tests reflect high-quality work, done only with EPA approval. (D29:7)

- EPA should base any evaluation of the human health effects of acetone on the National Toxicology Program drinking water study. (D14:i)

- Risk assessment of carcinogenic PAHs has changed dramatically over the past decade. Previously, all carcinogenic PAHs were assumed to be equipotent to benzo(a)pyrene. However, the weight-of-evidence clearly indicates that some PAHs are more potent than others. RPFs were devised to quantitatively assess the potency of a given PAH relative to that of benzo(a)pyrene. EPA (1993) evaluated the use of RPFs and published provisional guidance containing RPFs for six carcinogenic PAHs. Many other RPFs are available in the peer-reviewed literature. RPFs are typically multiplied by the oral cancer potency (Q*) of benzo(a)pyrene to determine the oral potency of the given carcinogenic PAH. Since the RQ Potency Factor (RQPF) is also an indicator of the carcinogenicity of a chemical, the RQPF could also be multiplied by the RPFs to determine the RQPF for other carcinogenic PAHs. Therefore, RPFs should be used in the WMPT ranking scheme to determine the cancer potencies (Q*) and RQPFs of carcinogenic PAHs for which RPFs are available. (D29A:6)

- The RQ Potency Factor (RQPF), which, unlike the RQ, is derived from cancer data only, represents a reasonable screening level estimate of the cancer potential of a chemical. However, it is more typical in cancer assessment to use a slope factor calculated by the linearized multistage model of carcinogenesis to characterize the cancer potential of a chemical. The RQPF may be useful as a quick screen since it requires fewer assumptions and is supposed to be relatively insensitive to the dose-response extrapolation model used. EPA may want to consider providing opportunities to conduct a more rigorous approach to cancer assessments, as part of follow-up assessments for chemicals classified as highly toxic due to carcinogenic endpoints. (D29A:7)

- The WMPT scores for human toxicity rely exclusively on measured and predicted data generated by EPA. The sole reliance on EPA databases unreasonably restricts the number of chemicals that can be scored. WMPT could

be enhanced with the addition of human toxicity data from non-EPA data sets, providing that data are included only from data sets that have undergone peer review and that these data sets are assigned to the appropriate data quality category. (E1:10)

- The Panel has sponsored extensive studies of hydroquinone under a TSCA Section 4 enforceable consent agreement (ECA), a voluntary TSCA testing program, yet none of these studies are included in the WMPT database. It would appear that the Agency is working at cross-purposes if it intends to encourage voluntary testing and then fails to utilize that data in subsequent initiatives. Of significant concern to the producers of hydroquinone is that while extensive and costly testing was completed for hydroquinone, the Agency appears to have ignored the TSCA test data in making its assessment of hydroquinone. EPA has been in possession of the studies for more than six years. EPA's failure to include these studies in the WMPT database results in the use of older, less reliable data, or worse, predicted values. That result is wrong and should be corrected. The Panel recognizes that many of the hydroquinone studies conducted under the TSCA testing program have not yet been included in EPA's IRIS database. However, that fact does not justify their exclusion from the WMPT database. EPA cannot in good conscience require industry to conduct studies, and then delay use of those studies for a period of several years merely because they have not yet been included in the IRIS database. EPA's failure to include these studies in the WMPT database creates the misleading impression that hydroquinone is a high-production volume chemical that has not been adequately tested. (D26:ii,3,4,5)

- The Panel has sponsored extensive studies of IPA under a TSCA section 4 test rule. Unfortunately, none of these studies are included or referenced in the WMPT database. EPA's oversight is surprising, because the Agency has previously apologized to the Panel for failing to include the TSCA Section 4 studies in an evaluation of potential hazards from exposure to isopropanol. EPA's failure to include these studies in the WMPT database creates the misleading impression that IPA is a high production volume chemical that has not been adequately tested. That impression is wrong and should be corrected. The Panel recognizes that the IPA studies conducted under the TSCA test rule have not yet been included in EPA's IRIS database. However, that fact does not justify their exclusion from the WMPT database. EPA cannot in good conscience require industry to conduct studies, and then delay use of those studies for a period of several years merely because they have not yet been included in the IRIS database. The Panel has striven to ensure not only that all data produced from its studies are submitted to EPA, but also that the data are published in the peer reviewed literature and that appropriate EPA staff are aware of the data. The Panel appreciates the Agency's need to rely on readily available scientific databases such as IRIS when evaluating specific chemicals. (D16:i,3,4,5)

- The Panels believe strongly that, if hydroquinone and IPA are included in the WMPT, then the underlying database should include the studies sponsored by the Panels under TSCA Section 4. Moreover, this objective can easily be accomplished because the Office of Pollution, Prevention and Toxics (OPPT) has already carefully reviewed all of these studies. The Agency's assessment of these studies is reflected in a risk management (RMl) review of hydroquinone, as well as in the Screening Information Data Set (SIDS) Initial Assessment Report (SIAR) prepared by the Panels and approved by EPA as part of the OECD SIDS program. (D26:5; D16:6)

- EPA should consider using a broader source of toxicology and environmental fate data than it is currently using in order to expand the number of chemicals it can process. (D55:2)

d. Fenceline Values

- The human toxicity "fenceline" values are generally inadequate because they fail to account for the severity of the effect induced by the chemical. Rather, the fenceline values, and the corresponding RfDs, RfCs, LOAELs and NOAELs consider only the dose level at which effects are seen, not the type or severity of the effect caused by the chemical. For example, two chemicals could have the same NOAEL and LOAEL (or RfD or RfC), but one could cause irritation while the other could cause severe birth defects. In other contexts, EPA has recognized the

necessity of considering both the level and the severity of the effect. This issue is particularly important for chemicals such as ketones, which cause only mild effects at high doses. (D17:4)

- These fenceline values are generally inadequate because they fail to account for the severity of the effect induced by the chemical. Rather, the fenceline values, and the corresponding RfDs, RfCs, LOAELS and NOAELs consider only the dose level at which effects are seen, not the type or severity of the effect caused by the chemical. For example, two chemicals could have the same NOAEL and LOAEL (or RfD or RfC), but one could cause irritation while the other could cause severe birth defects. In other contexts, EPA has recognized the necessity of considering both the dose level and the severity of the effect. (D25:5)

- EPA does not make clear the rationale underlying the fenceline values it established, and this criticism also is made of the UCSS by the Science Advisory Board. For persistence and bioaccumulation, EPA set fencelines to give a 1:1:1 distribution (high, medium, low) for a sample set of chemicals. For toxicity (RfD data), the fencelines were set to give a 1:2:1 distribution. No explanation is given as to why these are the appropriate distributions, or why they differ for the toxicity factor vis-à-vis the persistence and bioaccumulation factors. (D20:6)

- The toxicity fencelines do not take into account the potential levels of human or environmental exposure to particular chemicals (in addition to their persistence and bioaccumulation). Without this exposure component, the toxicity values are of limited relevance in assessing human or environmental risk. (D20:6-7)

e. Other

- The WMPT should be refined to provide more than one score when considering human health concerns so that users can identify and evaluate different health end points (for example a score for cancer and a score for noncancer effects) associated with different chemicals. (D77:2)

- The WMPT should be refined to include the health concerns of sensitive subpopulations and ideally consider and contain information on all potential human health risks (cancer, reproductive,...) and not just the most sensitive risk to the "general" population. (D77:2)

- All health effects are currently given equal weight, whether cancer or noncancer, regardless of the severity of the effect. The model should incorporate some algorithm to give additional weight to severe health effects. We suggest a simple switch, such as whether or not the effect is potentially life threatening. With this addition, the tool would provide greater differentiation and improve the focus on top priority issues, without adding undue complexity. (D64:3)

- The model does not adequately address different exposure routes. The schemes to rank different types of data sources into three categories (Appendix C) are all based on oral toxicity data; similar schemes for inhalation and dermal exposures are needed in the model. (D64:7)

- It is more reasonable and defensible to use permissible exposure limits that are based on the expected route of exposure for a chemical like methylene chloride. In addition, substantial epidemiological data should be considered for methylene chloride. This chemical should be assigned a human toxicity score of 1. (D32:11,12)

- EPA should check with facilities conducting 112(r) activities for clean air to see if they think acute toxicity should be included in the tool. The lack of acute toxicity data in WMPT, however, is not a problem as long as it is clearly stated in the user's guide. (S1s:26)

- Acute toxicity should be evaluated by the tool. (D55:5)

- The tool's information should consider and contain information on all potential human health risks (cancer, reproductive, etc.), not just the most sensitive. (D55:5)

- A given chemical may have conclusive data on the route of exposure that is of concern. It is more reasonable and defensible to use permissible exposure limits (PEL) that are based on the expected route of exposure for a chemical like methylene chloride, which is inhalation. The RfD assigns it a human toxicity score of 2, whereas the RfC would result in a score of 1. Epidemiological data should also be considered in a weight-of-evidence approach. If only one data point is used, it should be the most appropriate database on route of exposure, quality, and relevance of the data. (D32:6)

- The software should distinguish levels of toxicity (i.e., acute versus chronic) as well as degree of toxicity (i.e., known human carcinogens should be ranked higher than suspected human carcinogens)—otherwise, the data will be distorted and misused. (D54:3)

- The Agency's methodology for scoring toxicity may not be scientifically credible. EPA itself has previously recognized that there is no meaningful way to generalize toxicity across classes of compounds because chemicals within a category often differ significantly in physical and chemical properties, and hence, in toxicity. At best the human toxicity scores based on the human toxicity rankings represent a broad approximation of the toxicity of an individual chemical. Such an approach is not appropriate for ranking individual chemicals on a list that likely will be widely cited and relied upon as a popular source for the identification of a chemical's toxicity relative to other chemicals. (D20:15)

- There are several problems with the ranking scheme that need to be addressed, including overlaps between data that are used to determine the non-cancer and cancer potential of a chemical and how the ultimate toxicity of a chemical is determined. We recommend changes in BTEX and PAH toxicity scores (see Table 2 in comments of D29A). (D29A:4)

- The WMPT fails to account adequately for differences among chemicals in using chemical categories to assign toxicity rankings. (D27:ii)

6. Ecological Toxicity Scoring

a. Data Quality Hierarchy

- The toxicity data on individual chemicals ranked by the WMPT varies considerably in both quantity and quality. Other chemicals that have not had extensive testing, perhaps limited to a few acute toxicity studies in animals. By using the "best available" data for ranking a chemical by WMPT, EPA has created an arbitrary and systematic bias in the ranking of chemicals. For example, final chronic toxicity values when adjusted for EPA's highly conservative uncertainty factors are nearly always much higher than values based on acute toxicity data. Similarly, because EPA typically uses the highest PBT score when more than one data element is available, well tested chemicals will invariably score higher than the "data poor" chemicals. (Reference Chemical Manufacturer's Association/CCC comments, Subsection II C. 2. titled "The WMPT Penalizes Chemicals Having Well Defined Toxicity Profiles.") Pesticides are subject to extensive testing and thorough evaluation by EPA for health and environmental risks as required by FIFRA for registration. As described by the Chemical Manufacturer's Association comments above, it appears that pesticides are penalized by higher rankings from WMPT simply because of the greater availability of test data. (D69:6)

- EPA used "Prescored Acute/Chronic Data" to assign ecological toxicity scores of 2 to 2EH and 1 to isobutyl acetate, isopropyl acetate and propanol. EPA, however, has provided interested persons absolutely no information on the basis for the prescored values for individual chemicals. Thus, the Oxo Process Panel is unable to provide meaningful comments on the application of this model to 2EH. The 2EH score should be withdrawn unless and until EPA makes the basis for the score available to the public in an easily accessible and transparent way, and provides a reasonable period for public comment. The WMPT also assigns amyl acetate, butyl acetate and propionaidehyde ecotoxicity scores of 2 based on their Aquatic Toxicity Reportable Quantity (RQs) of 1,000 pounds. The Panel strongly objects to these scores and seriously questions the validity of using RQs to rank any chemical. The SAB review of the UCSS indicated that use of the RQ was not appropriate, stating that the aquatic RQ is "[n]ot a very reliable source of direct toxicity." Indeed, the aquatic RQs for these oxo process chemicals were developed approximately 20 years ago, using the limited data available at that time. The RQ values therefore are quite outdated and should not be included in the WMPT. EPA instead should evaluate the available environmental fate and ecological toxicity data for these chemicals, which show that all of these oxo process chemicals pose a low ecotoxicity concern and should be assigned a ranking of one. (D25:ii, 12-13)

- Since indirect data sources are based on primary data sources, there is no reason to use indirect sources. The primary sources for these values should be used instead of the indirect values. FCVs and SCVs are based on the consideration of many data elements, but the use of adjustment factors to set "safe" levels will lower the chronic toxicity value from the experimentally determined value. Chronic toxicity data should be used to assign the ecological toxicity value instead of FCVs and SCVs which incorporate further manipulation of the toxicity data. This change would not reduce the number of chemicals with data, because the chronic toxicity data exist for those chemicals that have an FCV or SCV established. (D32:2)

- Ecotoxicity scores in the WMPT are based on secondary chronic values (SCVs) from EPA's Great Lakes Water Quality Initiative Tier II methodology. This methodology involves statistical manipulation which can lead to variance in the type and quality of the data used in the WMPT. (D27:21, 39)

- The WMPT ignores high quality ecotoxicity data that have been published in the peer reviewed literature or that have been developed or used by other EPA offices. (D20:i,3)

- The WMPT should base ecotoxicity scores on available animal and aquatic toxicity studies rather than on predicted, estimated or "prescored" values. For example, the WMPT should consider available aquatic toxicity data on nonylphenol (NP), nonylphenol ethoxylate (NPE), octylphenol (OP), and octylphenol ethoxylate (OPE) in

evaluating the ecotoxicity of these compounds. It is inappropriate for EPA to rely on "prescored acute data" to evaluate the ecotoxicity of compounds on which aquatic toxicity studies have been conducted. Indeed, the use of measured ecotoxicity data is endorsed by the ecotoxicity data hierarchy in the WMPT. Acute and chronic aquatic toxicity studies have been conducted on NP, NPE, OP and OPE. Measured data from studies such as these should always take precedence over predicted and "prescored" values and should be used by the WMPT to evaluate the relative ecotoxicity of individual compounds. (D20:ii,3,18)

- The ecological toxicity factor should be based on the worst case, stable reaction product for compounds which undergo hydrolysis or photolysis in a rapid time frame. (D37:iii)

- Give highest priority to actual toxicological data, rather than IRIS values and FCVs. IRIS data and FCVs introduce various policy decisions including safety factors so the data are less comparable than actual experimental data. The quality and relevance of the particular studies and whether they have been externally peer reviewed are keys to determining the data quality for a particular chemical. (D32:cover1)

- The ecological toxicity scoring places estimated chronic and SCVs above the measured chronic and acute toxicity values. The test data should take precedence over estimates. (D32:3)

- EPA has used flawed values for the phthalate esters, yet the draft WMPT classifies these flawed values as "high" quality (for instance, the secondary chronic values are rated as "high quality"). (D18:27, 35)

- Data that are designated as "high quality" may be flawed or incomplete, and the source of data used to score a number of chemicals is not specified. Thus, it is not possible to critique the validity of the underlying experimental data. For example, SCVs have not been subjected to public comment and may be based on either flawed or incomplete laboratory data. For benzoanthracene and benzopyrene, the SCVs are derived from a single daphnia toxicity test which was performed at exposure concentrations at or above the water solubility limit. Similarly, the SCV for benzene is dictated by a low LC_{50} value reported for rainbow trout. However, it is hypothesized that the data from this study may be confounded by benzene volatilization which occurred during the exposure, lowering the apparent exposure concentration by the end of the test, and thus, inflating the reported LC_{50} value. Anthracene provides another example since the SCV is based on only two acute fish toxicity tests. However, aquatic toxicity data are available for a number of other aquatic species (e.g., daphnia, artemia, algae). (D29A:7,8)

- The data quality descriptors assigned in WMPT to the ecological toxicity data are inconsistent with the data quality descriptors assigned to the human toxicity data. There is not an equivalent quality data source for ecological toxicity for IRIS, which is the highest quality data source for human toxicity. For consistency, all ecological toxicity should be assigned medium or low quality data descriptors. (S1s:30)

- The highest quality data elements for ecological toxicity should be data elements that are generated for ecological, not human, species. For example, direct toxicity to ecological species should be higher quality data than a data element generated from human consumption of ecological species. The high quality ecological toxicity data elements should only be those data elements derived from studies of direct toxicity to ecological species. (S1s:30, 33)

b. Data Sources and Accuracy

- The draft WMPT ecological toxicity score of 3 for BBP is based on a GLWQI Tier II SCV (0.019 mg/l) taken from the *ECO Update* (Docket N. MPCA-S0012). The Panel is aware that, in fact, an SCV of 0.019 mg/l was generated by EPA's Biological Technology Assistance Group (BTAG) for development of the "EcoTox Thresholds." The toxicity studies used by BTAG are not referenced or listed in any fashion in the ECO Update or in the docket for the draft WMPT, so that the Panel cannot comment on those studies. Measured acute aquatic

toxicity data for BBP, however, show that the LC_{50}/EC_{50} is generally greater than 1 mg/L -- two orders of magnitude higher than the SCV value (Staples et al., 1997a). Therefore, EPA should delete the SCV value for BBP from the WMPT. (D18: 68)

- The solubility of nickel and the associated FCV are dependent on the hardness of the water, a point that EPA seems to have overlooked in developing the WMPT and the Prioritized Chemical List. In assigning nickel an Ecological Toxicity score of 3 under WMPT, EPA utilized an FCV for nickel (0.029 mg/l) that was calculated for a water hardness of 50mg/l $CaCO_3$. But there is no acknowledgment of this point in the WMPT and no discussion of whether the Aquatic Toxicity Scoring Fencelines are intended to apply to water hardness-dependent metals like nickel at a water hardness of 50 mg/l $CaCO_3$, 100 mg/l $CaCO_3$, 150 mg/l $CaCO_3$ or some other level. (D56:17-18)

- The WMPT Aquatic Toxicity Fencelines were adopted directly from the Office of Pollution Prevention and Toxics' Use Clusters Scoring System ("UCSS"). The UCSS itself does not discuss the appropriate water hardness level for application to water hardness-dependent metal at a water hardness of 150mg/l CaCO3. The WMPT Aquatic Toxicity Fencelines should, therefore, be applies to nickel at a water hardness of 150mg/l CaCO3, as well. As discussed in the following section, when the appropriate water hardness adjustment is made, the FCV for nickel falls into the medium category for purposed of Ecological Toxicity scoring. (D56:18)

- In its National Toxics Rule, EPA calculated an FCV for dissolved nickel of 160 ug/l (0.16 mg/l) at a water hardness of 100 mg/l CaCO3. Applying EPA's formula for calculating FCVs for water hardness-dependent metals, the FCV for dissolved nickel in the National Toxics Rule would be 22ug/l (0.22 mg/l) at a water hardness of 150 mg/l CaCO3. The FCV for dissolved nickel using data from the Great Lakes Water Quality Initiative would be 52 ug/l (0.052 mg/l) calculated at a water hardness of 100 mg/l CaCO3 and 73 ug/l (0/073 mg/l) calculated at a water hardness of 150 mg/l CaCO3. The reason for the difference is that in the Great Lakes Water Quality Initiative, EPA considered test data that were not considered in the National Toxics Rule. In particular, eight sets of acute toxicity (LC50/EC 50) data were added to the database for nickel in connection with the Great Lakes Water Quality Initiative. Seven of the eight LC50/EC50 values (adjusted to a water hardness of 50 mg/l CaCO3) ranged from 66,100 ug/l toe 160,521 ug/l. The eighth value, an LC50 for the snail species Physa gyrina, was 416 ug/l, more than two orders of magnitude lower than the values in the other seven studies. This value was also far below any other acute aquatic toxicity value for nickel that had been reported previously. (D56:19-20)

- The Diisocyanates Panel believes that the available data support a score of 2 for TDI, as well as the 2,6-TDI and 2,4-TDI isomers. EPA should not rely on the acute data from the red sea bream (Pagrus major) to score the ecotoxicity of TDI. This is a non-standard test organism, available only in Japan, and this value reflects a significant departure from the acute values reported in other aquatic species, all of which indicate that TDI is of low to moderate ecotoxicity. The acute ecotoxicity data for TDI (and the 2,4-TDI isomer) are summarized in Table 2 below: (D19:12-13)

Table 2: Ecological Toxicity Studies for TDI and 2,4-TDI Isomer

Species	Time	Endpoint	Concentration	Reference
Daphnia magna	48h	EC50	12.5 mg/l	Tadokoro et al.
Mysidopsis bahia	48h	LC50	18.3 mg/l	Tadokoro et al.
Rainbow trout	96h	LC50	133 mg/l	Tadokoro et al.
Daphnia magna	21d	NOEC	>0.5 mg/l	Caspers et al.

- The data hierarchy in EPA's User's Guide indicates that chronic data are preferred to acute data. See User's Guide Appendix C at C-14. However, the WMPT does not appear to consider the high quality chronic aquatic toxicity study of commercial TDI (80% 2,4-TDI and 20% 2,6-TDI) conducted by Caspers et al. (1986). This

study reported a 21-day NOEC of >0.5 mg/l in Daphnia magna. This measured value is consistent with the Predicted Chronic GMACT Value of 0.51 mg/l for TDI and should be cited as the basis for the ecotoxicity ranking of 2 for TDI and the two isomers. (D19:13)

- The Ecological Toxicity Score for Benzophenone is 3. This score is based on Prescored Acute Data. The Prescored Acute Data is one of the parameters for which a definition, fenceline data or references are not available. We believe the following information obtained from the Hazardous Substances Databank (published by Micromedex) should be considered and this score modified accordingly: 96-hour LC_{50} Fathead minnow: 15 mg/L. (D71: 2)

- The WMPT for example uses only aquatic toxicity in its analyses of ecological toxicity, however, there is no consideration of whether materials are actually available to organisms in the aquatic environment. For example, Pendimethalin has a low solubility in water and binds tightly to soil particles which means even if present in water it rapidly disappears from the aqueous phase. This reduces the bioavailability to aquatic organisms and the risk of being harmed. Because Pendimethalin binds to the soil, sediment evaluations are much better indicators of risk than aquatic toxicity RQ for overall ecological toxicity. The SCV derived on GLWQI tier II methodology which relies on one species is ranked as a high data quality point. A Pendimethalin study on Midge survival resulted in low and no observable effect levels in the 0.1 - 1.5 mg/l range (England et al. 1994). This range fits the Aquatic Toxicity subfactor fencelines at the medium level. The risk from a variety of chemicals is tied to how those chemicals are available for exposure to humans and the environment. Different chemicals which have varying physical and chemical properties should be evaluated using indicators that reflect real potential exposure. The WMPT does not adequately address the overall exposure potential. (D36: 3)

- Table 4 presents aquatic toxicity data for DEHA. As for the higher molecular weight phthalate esters, DEHA shows no acute aquatic toxicity at levels up to its water solubility. In one study, an EC_{50} for *Daphnia magna* was reported at a level near the DEHA solubility limit. The same study also reported a NOEC for *Daphnia magna* of 0.024 mg/L and a LOEC of 0.052. It is quite possible, however, that these anomalous effect values reflect physical entrapment of the *Daphnia* in undissolved DEHA, rather than actual toxicity. The EC_{50} of 0.66 is right at the currently-available measured solubility or DEHA -- 0.78 ± 0.16 mg/L (Felder et al., 1986). As techniques for measuring low-solubility compounds have been refined over the past few years, solubilities often are found to be lower than previously reported. The QSAR predicted solubility for DEHA is 0.0005 mg/L, a value well below the reported *Daphnia* effect levels (EPIWIN Version 2.2 software, Syracuse Research Corporation, Syracuse, New York). (D18: 88-89)

- Clearly, given the large number of species for which there is no toxic effect at levels up to and including the saturation level, DEHA is not highly toxic. EPA should assign DEHA an ecological toxicity score of no more than 2, and possibly of 1. EPA also should update the DEHA entry as new data become available. If the measured solubility proves to be lower than the reported *Daphnia* effects, DEHA should be classified as having "no toxic effects at saturation." (D18: 88-89)

- *[Note: this information was provided in a tabular form in Appendix IV of the comment.]* Acute/Prolonged Toxicity to Fish: *Pimephales promelas* (Veith et al., 1983): LC_{50} (96 hr) = 9,640 mg/L. Acute Toxicity to Aquatic Invertebrates: *Daphnia Magna* (Bringmann and Kuehn, 1977): EC_{50} (24 hr) > 10,000 mg/L. Acute Toxicity to Aquatic Invertebrates: *Crangon crangon* (Bringmann and Kuehn, 1977) LC_{50} (48 hr) = 1,400 mg/L. Chronic Toxicity to Aquatic Invertebrates: NOEC (16 day) = 141 mg/L (Growth). Chronic Toxicity to Aquatic Invertebrates: NOEC (21 day) = 30 mg/L. (D16: Appendix IV)

- In some cases, EPA has listed values in the WMPT that are unreviewable. For example, information in the docket indicates that certain ecotoxicity scores were assigned according to data in the AQUIRE database. However, this

database lists multiple values for some chemicals and no values for others. EPA's statement that presenting actual values from commercial databases would violate copyright laws does not justify this error. (D18:15-16, 19, 36)

- EPA relied on "Prescored Acute/Chronic Data" to assign ecological toxicity rankings to several ketones but has provided no information on the basis for these pre-scored values, precluding meaningful comment. The commenter believes EPA should withdraw the prescored values unless and until EPA makes the basis for these scores available to the public in an easily accessible and transparent way, and provides a reasonable period for public comment. (D17:ii,15-16)

- Another example is based on EPA's use of "prescored acute/chronic data" to assign ecotoxicity rankings of 3 to diisononyl phthalate, diisodecyl phthalate, and di(2-ethylhexyl)adipate and a ranking of 2 to di-n-hexyl phthalate. The matrix of source information indicated that the values were from the AQUIRE database. This database contains multiple values for diisononyl phthalate and diisodecyl phthalate. Interested parties cannot review the data to evaluate the quality without knowing which of the multiple values were used to assign the "prescored acute/chronic data." No values for aquatic toxicity values were available in AQUIRE for di-n-hexyl phthalate or di(2-ethylhexyl)adipate. Therefore, no basis was available for the prescored value. (D75:14)

- The WMPT should be refined to include improved ecological data from readily available and "not so readily available" sources (for example little or no data is included on dioxin). (D77:2)

- The ecological toxicity score of benzophenone is 3 based on prescored acute data. The prescored acute data is one of the parameters for which a definition, fenceline data, or references are not available. We believe the following information obtained from the Hazardous Substances Database (published by Micromedex) should be considered and this score modified accordingly: 96-hour LC_{50}, fathead minnow = 15 mg/l. According to the fenceline data for measured acute LC_{50}/EC_{50} for Most Sensitive Species, benzophenone should have an ecological toxicity score of 2. (D71:1)

- The ecological toxicity score for sodium benzoate is 2 based on the measured acute LC_{50}/EC_{50} for Most Sensitive Species. We believe the following information obtained from the EPA AQUIRE database should be considered and this score modified accordingly. The 4-day LC_{50} value for *Daphnia magna* was determined to be >10,000 ug/l. The 4-day LC_{50} valued for fathead minnow ranged from 484,000 ug/l to >100,000 ug/l. (D71:2)

- The scoring of metals for ecological toxicity fails to acknowledge that many elemental metals and metal compounds do not dissolve in water or have very low solubility. Since a very large proportion of metal wastes consists of insoluble metal species, the WMPT's scoring of metals as highly toxic to aquatic organisms with correspondingly high rankings on the PCL will result in erroneous or misplaced priorities for waste minimization. In addition, the Panel is concerned that WMPT users will apply these overly conservative values and flawed assumptions to score the ecological toxicity of metal compounds that do not have completed aquatic toxicity data fields. (D43:18)

- Halogenated Solvents Industry Alliance notes the WMPT's treatment of 1,1,1-trichloroethane (CAS No. 71-55-6), which is assigned an overall score of 11 due largely to the score of 3 for the chemical's ecological toxicity. According to the WMPT, the ecological toxicity score results from a Secondary Chronic Value (SCV) of 0.062 mg/l. This score is inconsistent, however, with the other ecological toxicity values for the chemical contained in the WMPT (i.e., GMATC (most sensitive aquatic species) = 2.7 mg/l (2); aquatic toxicity RQ = 1,000 lbs (2); acute LC_{50}/EC_{50} (most sensitive species) = 11.1 mg/l (2)). Although EPA considers the quality of the RQ and the acute LC_{50}/EC_{50} data to be low, Exhibit C-8 in the background information indicates that these data are available for 24 and 71 percent, respectively, of the chemicals in the PCL. Only 5 percent of the PCL chemicals, on the other hand, have an SCV. More significantly, 17 percent of the PCL chemicals have GMATC data that is believed to be of equal quality to SCV data. Using any of the alternative ecological toxicity values for 1,1,1-

trichloroethane, the chemical would be given a toxicity score of 2 and an overall score of 10. The decision to use the SCV data appears to be based on the WMPT's overall assessment of the quality of the data. Although the resulting difference in scoring likely would be meaningless in a qualitative assessment scheme, it makes a significant difference in the current quantitative ranking. (D67:3,4)

- Moreover, in view of the weight of evidence on aquatic toxicity, it seems entirely inappropriate to give 1,4-dichlorobenzene a score of 3 in the ecological toxicity category. Indeed, this score may reflect simply the large body of data that has been generated with this compound. If the draft Tool fails to use a weight of the evidence approach to calculate the toxicity scores and instead simply uses the lowest no effect level, it will penalize chemicals for which producers have generated a thorough database when compared to chemicals with few studies. The data summarized in Appendix A demonstrate how the weight of evidence for environmental toxicity fail to demonstrate a high risk at general exposure levels. Appendix B contains 1,3-dichlorobenzene-specific information. Here again, 1,3-dichlorobenzene rapidly evaporates from water and is almost all found in the atmosphere. As with 1,4-dichlorobenzene, the data do not support a 3 score in ecological toxicity when the weight of evidence for ecological toxicity is considered. Finally, Appendix C contains information specific to 1,2,4-trichlorobenzene. While the material does not evaporate as rapidly as the dichlorobenzenes, the levels in the aquatic environment are far below toxic levels. (D68:9-10)

- For the chemical CAS No. 5989-27-5, the ecological toxicity score should not be a 3 without data to back up the score. Without data, the score should be no more than one. (D74:1)

- The Chlorobenzene Producers Association has submitted extensive information to EPA concerning several of the listed chlorobenzenes in connection with the Agency's 1996 consideration of a possible test rule for persistent, toxic and bioaccumulative materials under the Toxic Substances Control Act (TSCA). The information that the Chlorobenzene Producers Association provided to the Agency in that matter, including information about persistence, partitioning to the atmosphere, levels found in surface water, and toxicity levels in aquatic organisms is also relevant here. Appendices A, B, and C contain information relevant to 1,4-dichlorobenzene, 1,3-dichlorobenzene and 1,2,4-trichlorobenzene, respectively. (D68:7)

- On the Prioritized Chemical List, EPA has assigned elemental nickel an Ecological Toxicity score of 3, based on the Final Chronic Value ("FCV") for aquatic toxicity of nickel in the Great Lakes Water Quality Initiative. Aquatic toxicity is not an appropriate basis to rank nickel for purposes of waste minimization. Even if it were, the score of 3 would not be justified. Elemental nickel does not dissolve in water. Consequently, the FCV for dissolved nickel is not relevant to evaluating the ecological toxicity of elemental or metallic nickel. Moreover, because of its high value, nickel in its metallic or elemental form will almost always be recycled rather than disposed, so it would not present a significant threat of aquatic toxicity even if it were water soluble, which it is not." Since the vast bulk of nickel-containing wastes consists of insoluble nickel species, it makes no sense to base a waste minimization ecological toxicity score for nickel on the aquatic toxicity FCV for dissolved nickel. Nickel, therefore, should not be scored at all for Aquatic Toxicity—effectively receiving a score of zero. There are also two other problems with assigning nickel a score of 3 for Aquatic Toxicity. First, no consideration seems to have been given to the water hardness dependency of the FCV for nickel. Second, the Great Lakes FCV for nickel was calculated improperly because of reliance on a study that should not have been used. (D56: 14-24)

- The SAB review of the UCSS indicated that use of the RQ was not appropriate, stating that the aquatic RQ is "[n]ot a very reliable source of direct toxicity." Indeed, the aquatic RQs for methyl ethyl ketone and isophorone were developed approximately 20 years ago, using the limited data available at that time. The RQ values therefore are quite outdated and should not be included in the WMPT. EPA instead should evaluate the available environmental fate and ecological toxicity data for these chemicals, which show that both methyl ethyl ketone and isophorone pose a low concern and should be assigned an ecological toxicity score of 1. (D17:16)

- For a number of phthalate esters included in the WMPT, no ecotoxicity data are provided, and thus no score is included in the WMPT. Many of these chemicals are high volume commercial products for which extensive databases are available. EPA should ensure that these data are included in the WMPT. Other higher-molecular weight phthalate esters elicit no aquatic toxicity effects at concentrations up to and including their saturation levels. These should be included in the WMPT as lowest toxicity chemicals. (D18:90-91)

- EPA should evaluate the hazard of chemicals which rapidly volatilize from water or soil at significant rates on terrestrial rather than, or in addition to, aquatic organisms. (D37:iii)

- The ecological toxicity factor is driven by toxicity to freshwater fish and to a lesser extent, aquatic invertebrates. Further development of the tool must incorporate more hazard information representing other ecosystem components. (D37:iii)

- In 1985 Brush Wellman focused on the freshwater aquatic criteria for beryllium in the context of a rulemaking by the Ohio EPA to amend its water quality standards to reduce the aquatic life water quality criteria for beryllium from 1,100 ug/1 to a hardness dependent criteria ranging from 5.4 to 34 ug/1. Brush Wellman reviewed the data that the Ohio EPA had used to calculate its proposed revised criteria. Brush Wellman noted that the data were sparse—too sparse to properly calculate a water quality criteria. The chronic value for daphnia was a single data point, which could not be statically tested. Also, for bluegill, Ohio EPA was extrapolating a "slope" from a two data points, which was statistically improper. Moreover, some of the reported data appeared erroneous. While the toxicity of metals typically decreased as hardness increases, data the Ohio EPA was using reported that the toxicity of beryllium to daphnia increased as hardness increased. In order to investigate the reliability of these data, Dr. Arthur Buikema of Virginia Polytechnic Institute to conducted acute and chronic bioassays on daphnia magnae. Dr. Biukema's study (see attachment X), found a traditional relationship between hardness and the toxicity of a metal. Second, Dr. Buikema found that daphnia magnae were far more resistant to beryllium than the criteria had predicted. As a result of this study, the Ohio EPA adopted different water quality criteria, ranging from 1,000 to 14,000 ug/l and are orders of magnitude higher than the Great Lakes Water Quality Initiative Tier II criteria. (D15:6)

- A substantial body of data exists on the potential health and environmental effects of aryl phosphates, though much of the information appears not to have been used in the WMPT. (D21:3)

- The existing database does not reflect the wealth of good-quality data for phthalate esters that are available in peer-reviewed literature as well as EPA files. For example, all but one of the higher-weight phthalate esters were assigned an ecological toxicity score of 3 despite available chronic toxicity data for nine fish species that indicate no toxicity at concentrations within and up to their solubility limit. As another example, the WMPT uses secondary chronic values instead of final chronic values (which are based on fewer conservative assumptions) for Dimethyl phthalate (DMP), Diethyl phthalate (DEP), Dibutyl phthalate (DBP), and Butyl benzyl phthalate (BBP). (D18:27, 30)

- Although WMPT was based on some level of data quality assessment, the underlying ecotoxicity database does not necessarily reflect the wealth of relevant "good quality" toxicity data that are available in the published literature on BTEX and PAHs. (D29A:8,9)

- EPA's review of hydroquinone in the WMPT is not consistent with previous EPA assessments that expressly recognize that hydroquinone is a low concern for ecotoxicity. (D26:ii,3)

- EPA's review of IPA in the WMPT is not consistent with previous EPA reviews that expressly recognize that IPA is of low concern for ecotoxicity. (D16:3)

- By looking at acute toxicity results for many different aquatic organisms and then choosing the lowest value, the WMPT may give lower scores to chemicals that have been tested extensively than to chemicals that have been tested in only one or a few organisms. (D24:2)

- The sources are not revealed for many derived aquatic toxicity values. EPA cites its *Environmental Toxicity Profiles for Existing Chemicals* as the source for many data elements but these data are absent for numerous chemicals. (D27:52-53)

- The evaluation of aryl phosphate ecological toxicity is based on information that has not been made publicly available. Ecological toxicity scores should not be based on prescored acute data for which adequate information is not provided. (D21:i; D25:20)

- EPA relied on "Prescored Acute/Chronic Data" to assign ecological toxicity rankings to four oxo process chemicals but has provided no information on the basis for these pre-scored values, precluding meaningful comment. (D25:ii)

- Ethylene glycol butyl ether acetate (EGBEA) should receive an aquatic toxicity score of 1 rather than 2. The score of 2 is based on "Prescored Acute Data," but no indication for the basis of the "Prescored" value is made in the WMPT. The User's Manual states that structure activity relationships from OPPT models were used; however, this appears to be incorrect since the aquatic toxicity values for all other scored ethylene glycol ethers are 1. (D45:3-4)

- The predicted chronic ecotoxicity value for 4,4'-methylenediphenyl isocyanate (MDI) is inconsistent with ecotoxicity studies that show 4,4'-MDI has very low aquatic toxicity. The ecotoxicity score should be based on the available aquatic toxicity data for 4,4'-MDI and polymeric MDI (not on the toxicity of the hydrolysis byproduct). These data support an ecotoxicity score of 1 for 4,4'-MDI. (D19:i,3,7-8)

- 4,4'-Methylenediphenyl isocyanate (MDI) reacts rapidly with water to form predominantly inert polymeric polyurea products, and only very small amounts of MDA (the hydrolysis product) are formed. If EPA has concerns regarding the potential ecotoxicity of aquatic exposure to very small amounts of MDA, EPA should separately review MDA's toxicity, persistence and bioaccumulation. Moreover, aquatic toxicity studies have been conducted on MDA. Therefore, any evaluation of MDA's potential ecotoxicity also should be based on the actual data and not on predicted values. (D19:7)

- The ecotoxicity score of 2 for toluene diisocyanate (TDI) should be based on high quality chronic ecotoxicity data and not on predicted chronic or atypical acute values. EPA should not rely on the acute data from the red sea bream (Pagrus major) to score the ecotoxicity of TDI. This is a non-standard test organism, available only in Japan, and this value reflects a significant departure from the acute values reported in other aquatic species, all of which indicate that TDI is of low to moderate ecotoxicity. The data hierarchy in EPA's User's Guide indicates that chronic data are preferred to acute data; however, the WMPT does not appear to consider the high quality chronic aquatic toxicity study of commercial TDI (80% 2,4-TDI and 20% 2,6-TDI) conducted by Caspers *et al* (1986), which should be cited as the basis for the ecotoxicity ranking of 2 for TDI and the two isomers. (D19:ii,3,12-13)

- The ecotoxicity scores rely on contractor reports and scoring models and methodologies that are not readily available for public review and comment. EPA and the WMPT have not provided adequate or accessible information to permit meaningful public comment on these parameters. (D20:i,3)

- EPA should not rely on Environmental Toxicity Profiles that selectively summarize available data and do not provide citations, methods or support for the values and conclusions presented. It is not clear whether these

Profiles also are used in connection with other EPA activities and initiatives. The Profiles have not been subject to scientific peer review or made available for public review and comment. Moreover, the Environmental Toxicity Profiles do not identify the sources of the data that are summarized and do not provide adequate information regarding the models, assumptions and sources on which EPA relied to derive predicted values, concern criteria and other conclusions. The data summaries presented in the Environmental Toxicity Profiles also are woefully incomplete. They omit peer reviewed data and other high quality studies, including data developed by EPA itself. The Environmental Toxicity Profile for octylphenol (OP) (CASRN 140-66-9) is particularly egregious. It states, without support or explanation, that OP "should be banned for all uses resulting in water releases." This regulatory conclusion is irresponsible and scientifically indefensible. It has no place in the Environmental Toxicity Profile and should be withdrawn. (D20:ii,3,18-20)

- Ecological toxicity scores should not be based on prescored acute data for which inadequate information is provided. The AQUIRE database is incomplete and omits important data. Moreover, EPA has not made the reports, models and other sources on which the ecotoxicity scores were based readily available for public review and comment. Insufficient information was provided to permit an understanding of the ecotoxicity values that were based on the "Prescored Acute Data." Thus, the commenter was unable to provide meaningful comments on the application of this model to the alkylphenols (APs) and alkylphenol ethoxylates (APEs). (D20:17-18)

- The Ecological Toxicity Score for beryllium is 3. This score is unsupported and should be reduced. This score appears to be derived from a Great Lakes Water Quality Initiative Tier II criterion of 0.0051000 mg/l. This criterion was calculated based on exposure to beryllium sulfate. The Ambient Water Criteria for Beryllium (EPA October 1980). Hence, any Ecological Toxicity Score in the Chemical Data Summaries should be established for beryllium sulfate and not for beryllium. Furthermore, more recent data, not considered in the calculation of this criterion, show that it is too conservative for beryllium sulfate. (D15:5)

- It is important to note that all aquatic studies have utilized soluble compounds of beryllium. The most common forms of products containing beryllium are very insoluble. Beryllium in the soluble forms is rarely used commercially. (D15:6)

- EPA should withdraw the ecological toxicity scores from the WMPT until it can base such scores on publicly available information. The Matrix of Source Information placed in the docket indicates that these values came from the AQUIRE database, which is incomplete and omits important data. For chemicals with more than one data entry in AQUIRE, one cannot divine which values were the basis for EPA's prescore. EPA has not provided citations for the data that support its prescores, much less placed the data in the docket. (D21:11-12)

- Similarly, EPA should evaluate the actual ecological effects data on amyl acetate, butyl acetate and propionaldehyde instead of relying on outdated and inaccurate RQs to set ecological toxicity scores. (D25:20)

- Aquatic toxicity is based on EPA's "Pre-Scored Acute Data" model, which is not subject to verification. (D24:2)

- Ecological toxicity data come from both nominal and measured test concentration studies. Studies often have weaknesses that limit their applicability and comparability (e.g., studies with test concentrations above chemical solubility limits, tests conducted at concentrations up to 1,000 times the environmentally relevant concentrations, and test conditions worse than those in the environment). Before using data, the data should be evaluated for relevance and converted to a comparable metric. (D32:4)

- Silver is given an ecological toxicity score of 3 based on an aquatic toxicity value derived from silver nitrate. Silver is not toxic to aquatic life and should be assigned an aquatic toxicity score of 1. (D32:9)

- Many of the values used in the WMPT for ecotoxicity have not been peer reviewed and do not reflect the wealth of toxicity data available concerning a particular compound. Simple structure activity relationship models have been used in lieu of better, actual measurement data that is available. Some databases utilized (such as AQUIRE) are incomplete or outdated. Much of the ecotoxicity data available today are not used in the WMPT, including data that EPA itself has generated and data generated in support of OECD and European Union (EU) risk assessments. For example, data from non-peer reviewed studies by Suter et al (1994 and 1996) on di-2-ethylhexyl phthalate (Di(2-ethylhexyl)phthalate (DEHP)) have been used in the WMPT. Numerous studies performed worldwide have shown results contrary to those used in the WMPT, namely, that Di(2-ethylhexyl)phthalate (DEHP) produces no aquatic toxicity at levels up to and including its saturation concentration. (D27:38-40)

- The use of aquatic toxicity studies well in excess of the water solubility of a particular compound is inaccurate and scientifically indefensible. EPA's methods in developing criteria for protecting aquatic organisms for low solubility compounds are inadequate. Such compounds should receive no ecotoxicity score or a score of zero; there is no other scientifically defensible score. (D27:41, 80)

- EPA has calculated different ecotoxicity scores for similar compounds of low toxicity. For example, di-2-ethylhexyl phthalate is given a score of 3, while di-n-octyl phthalate is assigned a score of 1; these compounds have nearly virtually identical chemical structures. (D27:41-42)

- Non-comparable data sources are used to develop ecotoxicity scores; both acute and chronic data are used. (D27:45-46)

- By using the lowest recorded value to rank chemicals for aquatic toxicity, EPA introduces inconsistency into the WMPT. For example, two chemicals of essentially equal toxicity may have very different ecological toxicity ranks because data for one relates to effects in bluegills, and a second to effects in *Ceriodaphnia*. (D27:46-47, 80)

- For ecological toxicity scores, the WMPT ignores the advice of the SAB and uses incomparable and outdated data for phthalate esters. The extensive database that exists on phthalate esters is largely ignored. (D18:ia, 2-3, 19)

- Extensive aquatic toxicity studies show that, generally, phthalate esters have relatively low toxicity toward aquatic species. In fact, the high molecular weight phthalate esters elicit no toxic effects even at saturation. However, the WMPT does not reflect this. (D18:26)

- The use of derived ecological toxicity endpoints in the WMPT is not appropriate for relative scoring due to incomparability of parameters (e.g., some reflect measured data from toxicity tests while others are based on statistical analysis of available toxicity data). EPA should select base parameters that are comparable; acute aquatic LC_{50} values based on *Daphnia magna* and fathead minnows probably provide the broadest basis for comparison. The use of derived values penalizes well-tested chemicals; the aquatic toxicity RQ should not be used at all; these are derived from outdated data that were available 20 years ago. (D18:27, 27-29)

- The validity of aquatic toxicity data has not been critically assessed. In particular, it has not been examined as to whether appropriate aquatic toxicity data below the water solubility limit are being used. (D18:27)

- The databases used for the WMPT are not clearly referenced. (D18:27)

- No mechanism has been provided to assess the validity or completeness of the values entered for aquatic toxicity data for the phthalate esters; as a result, many of the toxicity values entered are based on flawed and incomplete data. In particular, EPA should reject use of the SCV values taken from Suter and Mabrey (1994) imported via the ECO Update (Docket Number MPCA-S0012). These values are inappropriate because only a limited portion

of the data for phthalate esters is utilized and because the data that is used is flawed and incomplete. (D18:34-35) Specifically, EPA should delete the SCV value for Di(2-ethylhexyl)phthalate (DEHP). (D18:59-60)

- EPA should delete the SCV value for Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diethyl phthalate (DEP), and Dimethyl phthalate (DMP), which are inaccurate. (D18:68, 72, 78-79, 82)

- Higher molecular weight phthalates (those with six or more carbons in the alkyl chain) should be assigned the lowest ecological toxicity scores. These compounds have very low solubility in water, and studies in the literature support the conclusion that these compounds do not elicit acute or chronic toxicity at the water solubility limit (they cannot achieve the critical body burden needed to cause toxicity). These compounds should use a zero score if possible; under the current WMPT methodology, the score should be 1. (D18:30-34) This applies specifically to:
  -Diiodecyl phthalate (DIDP). (D28:47)
  -Diisononyl phthalate (DINP). (D18:50)
  -Di-n-hexyl phthalate (DnHP). (D18:63)

- For Di-n-octyl phthalate (DnOP), an ecological toxicity score of 1 has been assigned, which commenter agrees is the correct score (unless a zero score is adopted). (D18:54)

- For Diiodecyl phthalate (DIDP) and Diisononyl phthalate (DINP), the ecological toxicity score is based on "prescored chronic data" and "prescored acute data;" this is impossible to evaluate and these values should be deleted. The Diiodecyl phthalate (DIDP) value appears to be based on a study whose authors concluded that the observed effects were an artifact.. (D18:46-47, 49)

- For Di-n-hexyl phthalate (DnHP), the ecological toxicity score is based on "prescored chronic data" which appears to be derived from a flawed study. This value should be deleted. (D18:62-63)

- For Di(2-ethylhexyl)phthalate (DEHP), the GMATC value should be deleted in the WMPT since this value is likely based on an invalid study. Also, the measured acute LC_{50}/EC_{50} included in the WMPT is derived from a flawed study and should be deleted, as should the same value for Dibutyl phthalate (DBP). (D18:60-61, 73-74)

- For Di(2-ethylhexyl)phthalate (DEHP), EPA placed in the docket information that predicts no ecological toxicity. Therefore, EPA should assign the lowest ecological toxicity score, 1, to Di(2-ethylhexyl)phthalate (DEHP) (unless a zero score is included in the WMPT). (D18:61)

- The aquatic RQ values are not reliable sources and should be deleted. Specifically, they should be deleted for:
  -Butyl benzyl phthalate (BBP). (D18:68)
  -Dibutyl phthalate (DBP). (D18:73)
  -Diethyl phthalate (DEP). (D18:79)

- Under the WMPT methodology, the ecological toxicity score for Butyl benzyl phthalate (BBP) should be revised from 3 to 2; this is a more accurate reflection of the available LC_{50} values. (D18:69)

- Under the WMPT methodology, the ecological toxicity score for Dibutyl phthalate (DBP) should be revised from 3 to 2; this is a more accurate reflection of the available LC_{50} values. (D18:74)

- For Diallyl phthalate (DAP), EPA should delete the GMATC values and the prescored acute value since it is impossible to discern the sources of these values from the docket material. EPA should assign an overall ecological toxicity score of 2. (D18:75-76)

- For Diethyl phthalate (DEP), the measured acute LC_{50}/EC_{50} value appears to be derived from inaccurate data and should be deleted. Under the WMPT methodology, Diethyl phthalate (DEP) should be assigned a low ecological toxicity score. (D18:79-80)

- EPA's score of 1 for phthalic anhydride (PA) is valid. (D18:85)

- EPA should delete prescored values for Di-(2-ethylhexyl)adipate (DEHA) and substitute a more refined evaluation of potential toxicity. Given the large number of species for which there is no toxic effect at levels up to and including the saturation level, Di-(2-ethylhexyl)adipate (DEHA) is not highly toxic. Therefore, EPA should assign an ecological toxicity score of no more than 2, and possibly of 1. (D18:87-89)

- The source of data used to score a number of chemicals is not specified so that it is not possible to critique the validity of the underlying experimental data. (D29A: 9)

- It is well recognized that hydrocarbons, such as BTEX and PAHs, elicit ecotoxicity through a non-specific mode of action referred to as non-polar narcosis or "base-line" toxicity (McCarthy et al., 1991; McCarthy and Mackay, 1993). This latter term reflects the fact that chemicals operating by this mechanism represent the least toxic class of chemicals (Bradbury et al, 1990; Veerhar et al., 1992; Jawroska and Scholtz, 1993). Quantitative structure activity relationships (QSARs) have been developed for a diverse range of aquatic organisms to predict the ecotoxicity of non-polar narcotic chemicals (van Leeuwan et al., 1993). These efforts indicate that ecotoxicity demonstrates a consistent relationship with hydrophobicity as measured by K_{ow}. As K_{ow} increased, toxicity increases (i.e., LC_{50} decrease) to a point where water solubility constraints preclude toxicity. Above this point, toxicity is not expected since the water solubility of the chemical is not sufficient to allow the test organism to achieve a critical body burden necessary to elicit an adverse effect. To illustrate the ecotoxicity potential of BTEX and PAHs, acute and chronic toxicity estimates for daphnia, fish, and algae were calculated using EPA's ECOSAR program (Clements and Nabholtz, 1995) (results summarized in Table 4 of comments). Results were then used to develop ecotoxicity scores using the fencelines in WMPT. This analysis demonstrates that, for a number of chemicals, the proposed WMPT scores are inconsistent with EPA's ECOSAR results and thus of questionable validity. The ecotoxicity scores (for benzene, xylene isomers, acenaphthene, acenaphthylene, 2-methylnapthalene, 1-methylnaphthalene) are not internally consistent and do not accurately reflect the relative ecotoxicity potential for even the very limited set of chemicals examined. (D29A:9,10)

- Inconsistencies arise from the scoring method used in WMPT, which relies upon various toxicity endpoints (e.g., measured acute and chronic data for the most sensitive species as well as derived endpoints, such as SCVs or FCVs, may be combined). Derived endpoints are based on a statistical analysis of available aquatic toxicity data for a specific chemical. As a result, the basis for ranking the relative ecotoxicity potential of different chemicals becomes inconsistent when varying amounts of data are available. Moreover, the proposed scoring system tends to penalize "data rich" chemicals for which sufficient good quality data are available to support the calculation of a derived toxicity value which is intended to protect "most species most of the time." Comparing data rich chemicals with data poor chemicals also is contrary to the tiered hazard assessment paradigm in which the availability of more data serves to reduce (not increase) conservatism. The scoring system employed by WMPT could discourage stakeholders from generating aquatic toxicity information on chemicals of interest. (D29A:10,11)

- Ecotoxicity scores for most of the high molecular weight PAHs are based on QSAR-based chronic fish toxicity estimates. However, in many cases, the QSAR predicted effects concentration exceeds the water solubility of the chemical. Ecotoxicity would not be expected due to water solubility cut-offs, which occur at approximately 20 micrograms per liter (see Table 4 of comment). However, even this extrapolation assumed that the ecotoxicity QSAR is strictly linear. Experimental data suggest that toxicity QSARs often exhibit a curvature above the water solubility cut-off which tends to shift towards slightly higher water solubilities the point of demarcation between chemicals that elicit toxicity from those that do not. This is supported by the lack of chronic toxicity observed for

hydrophobic chemicals with log K_{ow} values above ca. 5.5 (Nebeker, 1989; Donkin et al., 1993; Parkerton, 1996). These studies suggest that all PAHs above and including chrysene will not elicit chronic ecotoxicity. This conclusion is supported by the lack of "positive" toxicity test results for high molecular weight PAHs in contrast to that of lower molecular weight PAHs. These poorly water soluble chemicals should be assigned an ecotoxicity score of 0 rather than 1. This will allow insoluble chemicals which cannot elicit toxicity at saturation to be differentiated from highly water soluble chemicals that exhibit toxicity only at very high concentrations. (D29A: 11)

- EPA has tentatively assigned a ranking of 3 to hydroquinone for ecotoxicity, indicating EPA believes hydroquinone presents a high ecotoxicity hazard. Any such suggestion, however, is simply wrong. The available data show that hydroquinone is acutely toxic to aquatic species, but its overall ecological health profile is benign because hydroquinone rapidly degrades in wastewater treatment plants, and it is not present in waste streams at significant concentrations. Accordingly, hydroquinone does not present a chronic ecological toxicity hazard. Because WMPT is designed to rank chemicals for chronic hazards, and hydroquinone does not persist in the environment long enough to pose a chronic hazard, the Panel believes that hydroquinone presents a low concern for ecotoxicity. The Panel's assessment is supported by the evaluation contained in the SIAR prepared for hydroquinone under the OECD SIDS program. The United States is the sponsoring country for hydroquinone, and the SIAR and underlying SIDS dossier were prepared initially by the Panel but were carefully reviewed, edited and approved by EPA. The SIAR concludes, "Environmental effects are not a concern due to the ready biodegradability and photodegradability of the substance." Id. at 2. Thus, hydroquinone simply should not be a significant concern for ecotoxicity. The Panel believes the ecotoxicity ranking for hydroquinone of 3 is arbitrary and scientifically indefensible; it should be changed to 1. (D26:5,6)

- EPA has tentatively assigned a score of 2 to isopropanol for ecotoxicity, indicating EPA believes IPA presents a medium ecotoxicity hazard. Three separate EPA documents demonstrate that IPA presents a low concern for ecotoxicity. The first document is an RM1 Risk Assessment on IPA prepared by OPPT in June 1996 (Appendix 111), which concludes, "Available data support a low concern for isopropanol ecotoxicity." Id. at 9. The second document is the SIAR prepared for IPA under the OECD SIDS program in March, 1997 (Appendix IV). The US is the sponsoring country for IPA, and the SIAR and underlying SIDS dossier were carefully reviewed, edited, and approved by EPA. The SIAR addresses the environmental fate and effects of IPA, and explicitly recognizes that isopropanol "is not expected to persist in the environment," and "presents a low potential hazard to aquatic or terrestrial biota." Id. at sections 2.1 and 4.0. The third document is a "Use and Exposure Profile for Isopropanol" prepared by OPPT in April 1997 (Appendix V), which expressly recognizes that isopropanol does not persist in the environment. Specifically, the document notes the following: (1) "An overall removal of 98 percent is predicted [during secondary wastewater treatment] because significant biodegradation is expected;" (2) "Isopropanol is expected to be readily biodegraded in aerobic and anaerobic environmental settings;" (3) "isopropanol is not expected to sorb to soils or sediment;" and (4) "the estimated volatilization half-life from a model river is 2.5 days. However, volatilization will be mitigated by the relatively rapid rate of biodegradation expected (half-life on the order of 1 day)." Id. at Section 1.2. These three EPA documents demonstrate conclusively that IPA is not a significant concern for ecotoxicity, and therefore, the Panel believes the ecotoxicity score for IPA should be changed to 1. (D16:7,8)

- Silver (7440-22-4) is listed as possessing a Class 3 toxicity. This is incorrect; silver should be listed as a Class 0 toxicity, with the exception of fish because silver is toxic to gills. Animals without gills are not affected by silver. Silver-copper sanitation systems have a long proven record for marine mammal exhibition pools. The Gulfarium, Fort Walton, FL, uses this system with sea water, the natural environment for marine mammals. The Curator of Animals observed that the silver-copper treated sea water in which sea lions, harbor seals, gray seals, and other mammals live has produced far fewer skin problems and avoided developing eye problems formerly seen in heavily chlorinated pools. With a silver-copper ion system, chlorine is still used as an oxidizer, but at about an 80% reduction. The Curator noted that silver-copper treated sea water retains its sanitation effects far longer than

chlorinated water, and silver-copper treated sea water holds down algae. Chlorine-based systems provide only a temporary sanitation because the hot Florida sun kills chlorine and evaporates it. Thus, chlorine must be added continuously to the pool in order to maintain its required sufficient strength, resulting in an environment not really healthy for sea mammals. With the use of silver-copper treatment and proper operation of the filter systems, the pools never had coliform counts even close to the limits imposed by the federal government. No evidence of toxicity has been observed in any of the animals. (D51:3,4)

c. Consideration of Additional Sources of Ecological Toxicity Data

- The aquatic toxicity concern for sodium dichloroisocyanurate should be reduced to low concern. The aquatic toxicity of H_3CY and its sodium salt, NaH_2CY, has been extensively studied and data indicate that they are classified as "practically nontoxic" with no LC_{50} less than 655 mg/l, and most LC_{50} values in the thousands of parts per million; see attached table 1. These values easily meet the 1 - low concern criteria in the WMPT (Appendix C, page C-24). This indicates that, although the sodium dichloroisocyanurate carrying two chlorines exhibits the same high acute aquatic toxicity as chlorine itself, the hydrolysis products are very nontoxic in the environment. (D59:4)

- There is often additional information and data in the open scientific literature or in EPA databases under programs such as TSCA Section IV that possess equal or greater utility for assessing human health and ecological risks. (D32:1)

- EPA should consider using a broader source of toxicology and environmental fate data than it is currently using in order to expand the number of chemicals it can process. (D55:2)

- Acute toxicity should be evaluated by the tool. (D55:5)

d. Fenceline Values

- EPA does not make clear the rationale underlying the fenceline values it established, and this criticism also is made of the UCSS by the Science Advisory Board. For persistence and bioaccumulation, EPA set fencelines to give a 1:1:1 distribution (high, medium, low) for a sample set of chemicals. For toxicity (RfD data), the fencelines were set to give a 1:2:1 distribution. No explanation is given as to why these are the appropriate distributions, or why they differ for the toxicity factor vis-à-vis the persistence and bioaccumulation factors. (D20:6)

- The toxicity fencelines do not take into account the potential levels of human or environmental exposure to particular chemicals (in addition to their persistence and bioaccumulation). Without this exposure component, the toxicity values are of limited relevance in assessing human or environmental risk. (D20:6-7)

- The fencelines for measured acute data are too broad. (D18:80)

e. Other

- Due to the concerns we have expressed in this letter, Reilly recommends that the WMPT and the Draft PCL be abandoned by the EPA. If the Agency refuses to abandon these proposals, Reilly recommends that the tools be substantially revised to correct the flaws which have been identified in these and other comments received by EPA. (D76:7)

- The acute aquatic toxicity of sodium dichloroisocyanurate is due to the release of chlorine from the molecule, but this effect quickly dissipates in the environment, with the resultant H_3CY and chloride exhibiting very little aquatic

toxicity. Acute aquatic toxicity issues related to chlorine are being well addressed under the Clean Water Act NPDES permit program. Therefore, a rating of 1 - low concern is recommended. (D59: 6)

- The aggregation and scoring approach used in the Tool requires close inspection and critical review by risk assessment experts. Single measures for human toxicity and ecological toxicity are wholly inadequate to represent the range of toxicological elements needed to characterize the hazard of a given chemical under a reasonable range of use scenarios. The single measure inappropriately aggregates very dissimilar and diverse endpoints, mechanisms of action, organisms (for ecological scores), dose-responses, test protocols, and conditions. Indeed, the scoring system displayed in Exhibit 1-2 is in basic conflict with guidance for effects assessment and dose-response evaluation given EPA's Draft Guidelines for Ecological Risk Assessment. (D30:7)

- The use of the default 1/10 acute to chronic ratio introduces and unacceptable degree variability which is not represented in the final ecological toxicity score. (D37:iii)

- WMPT should show the animal species that are represented by the AQUIRE data (i.e., the measured chronic values, EC_{50}, LC_{50} for the most sensitive species). It would also be helpful to be able to enter data for species native to a local area or state if the data in the system are for non-native species. (T3:1)

7. Mass Scoring

- The consortium concluded that county-wide databases do not necessarily provide a good overview of pollutants in Santa Clara County. For example, the San Jose/Santa Clara WPCP is under regulatory pressure to lower Nickel and Copper in their final effluent. Therefore, they have monthly sampling of trace metals at their facility. They are not under regulatory pressure for organic chemicals, and they monitor these chemicals annually. Similarly, the TRI air data does not include information from mobile air sources or small emitters. The consortium expressed concern that the data from the WMPT might be misinterpreted because of the paucity of complete databases in the county. An investigator who is inexperienced could use the WMPT results without fully understanding the limitations of the databases. All databases have limitations that need to be understood and specified in a report. An illustration of how a database should be evaluated for use in the WMPT is included in the Approach 3 section of the main report. (P1:9, 10, 29, 30, 46)

- The log scale may tend to understate the real difference in potential risks between two or more chemicals, such as comparing a large mass of a low ranked chemical (e.g., 6) with a small mass of a high ranked chemical (e.g., 18). The tool should instead amplify the difference. Any mass amount of a highly toxic chemical should generate a higher mass score than the same mass amount of a lower ranked chemical. A solution to this problem may be to use different mass scales for each ranking level (e.g., 6-18). (P1: A-8, A-9)

- The Tool's treatment of "exposure"—using crude estimates of chemical mass released- is wholly inadequate for risk assessors to consider the suite of factors necessary for determining exposure to humans or ecological receptors. According to EPA's Draft Guidelines for Ecological Risk Assessment, "exposure characterization describes the contact or co-occurrence of stressors with ecological receptors...based on measures of exposure and of ecosystem and receptor characteristics." The pattern of co-occurrence" is described in the Guidelines as "the intensity and temporal and spatial extent of exposure in a form that can be compared with the stressor-response profile generated in the effects assessment." Because the Tool fails to relate chemical releases in any way to specific ecological receptors, particularly in a manner which describes the intensity, temporal, and spatial extent of exposure, the Tool fails to follow the fundamental criteria for ecological risk assessment as defined by EPA's Office of Research and Development. (D30:3)

- The relative masses of chemicals generated are not proportional to the likelihood of releases of those chemicals to the environment. This line of thought smacks of the issues raised by the EPA's proposed Chemical Use Inventory initiatives, where industry maintains that chemical use reduction is in no way equivalent to reduction of emissions or wastes, and efforts toward that end effectively hobble the innovation and creativity of the chemical industry. (D76:2)

- EPA should remove the "mass" component from the WMPT or at least not apply it to low ranking compounds. Use of the "mass" component could produce the environmentally detrimental result of focusing waste minimization efforts on low toxicity, non-bioaccumulative, non-persistent chemicals simply because they are used in large quantities. The commenter recognizes that it is appropriate for a facility to consider the volume or mass of each waste when developing a site-specific waste minimization plan. However, it is not appropriate to consider volume on a national level in a way that causes low toxicity compounds to be inappropriately identified as high priority targets for waste reduction efforts. (D17:ii,24-26,28)

- The mass of the chemical produced, used or released clearly has a major impact in determining the "real world" potential for exposure either to humans or ecosystems. Without mass or concentration data, the WMPT ranking is strictly a hazard-based assessment. (D30:5)

- To provide greater accuracy in the ranking, the mass of the chemical in waste should be included in ranking the chemicals, as mass waste will have the greatest impact in determining the "real world" exposure potential.

Without the mass data, the WMPT ranking is really a potential hazard assessment tool and not a potential risk assessment tool. (D34:2-3)

- EPA should allow a number of different scenarios using mass data to be entered and viewed without making a permanent change to the database. This will provide a more useful tool and allow for the assessment of varying scenarios. (D36:6)

- It is appropriate for a facility to consider the volume or mass of each waste when developing a site-specific waste minimization plan. However, it is not appropriate to consider volume on a national level in a way that causes low toxicity compounds to be inappropriately identified as high priority targets for waste reduction efforts. (D25:19)

- WMPT fails to accurately reflect relative risk because the mass component is incomplete. In particular, mass should reflect environmental loadings, taking into account waste treatment and other waste management practices. (D49:3, 13)

- The user's guide states that WMPT is a risk-based screening system or a simplification of the risk paradigm (i.e., it takes into account both toxicity and exposure when determining relative risk). Even given that it is a simple screening tool not designed to perform complete, site-specific quantitative risk assessments, the system actually ends up ranking chemicals on the basis of hazard more than risk. The difficulty appears to be in the manner in which mass is accounted for. One of two actions should be taken: (1) abandon the use of mass in rank ordering, and more precisely refer to this as hazard rankings, thereby allowing site- or process-specific mass amounts to be entered by individual risk managers, or (2) incorporate mass into the risk ranking more explicitly and transparently, again on a site-specific level, to allow risk managers to select and direct their chemical-minimization methods more efficiently for their facilities or processes. (D29:2)

- The WMPT incorrectly assumes that mass translates into increased exposure. The mass factor should be deleted from the WMPT. It is not valid for EPA to assume that the "potentially releasable" amount of a chemical (equal to the mass of the chemical in wastes) is a realistic measure of release. This component of the WMPT does not account for the bioavailability of a chemical. Also, the mass factor fails to consider route of release; this may have an impact on persistence and environment exposure potential. (D27:44-45, 77)

- The WMPT should not penalize chemicals such as acetone that are used in large quantities precisely because of their favorable environmental attributes. EPA therefore should remove the mass component from the WMPT, or at least not apply it to low-ranking compounds. (D14:ii)

- The mass component should not be used to target chemicals under a waste minimization program that allegedly focuses on the most persistent, toxic, and bioaccumulative compounds. The mass component could have the opposite effect by focusing attention on "non-PBT" wastes due to their large quantities. EPA therefore should remove the mass component from the WMPT, or at least not apply it to low ranking compounds, to ensure that non-PBT chemicals such as acetone are not inappropriately targeted for reduction. (D14:11-12)

- As an alternative to mass, the WMPT could adopt a mechanism whereby users can compare measured or modeled concentrations of the chemical in environmental media against the NOEL for that chemical. Such a risk-based approach would ensure that non-PBT chemicals such as acetone are not inappropriately targeted. (D14:12)

- One participant noted that when mass is added to WMPT, waste minimization priorities are skewed if large quantities of a certain chemical are generated, even if the chemical has a low PBT score. For example, a chemical like acetone could receive a higher score than dioxin. EPA should caution users that their waste minimization priorities can be skewed if they input high mass values. (S1i:8; S1s:29)

- How will EPA meet its national goal of 50% reduction if WMPT gives high priority to a chemical with a score, for example of 18, but which is produced in minimal quantities. EPA should be sure to weigh subfactors and factors correctly so that WMPT does not too heavily weight chemicals that are used in small amounts. (S1i:13)

- If mass is incorporated into the algorithm, it could potentially increase the scale three times. (S1e:14)

- It does not seem that sufficient mass data exist to track and measure waste reduction progress at a national level. In addition, waste streams with particular chemicals might not be tracked because mass data are not available. Other sources of national level mass data such as TRI, BRS, and NHWCS could be used, but the data are limited. The feasibility of using mass data in determining the final list of chemicals if sufficient data does not exist is a concern. (S1e:20)

- To the extent that mass data are used along with the tool to track progress in reducing waste, ensure that high priority chemicals and waste streams are not missed due to a lack of mass data. (S1e:20)

- Mass should play an integral role in the scoring system and in developing the final list of chemicals against which to measure progress in reducing waste. Identify a surrogate for mass to score chemicals when mass data are not available. (S1e:20)

- Mass data are not adequately taken into account in WMPT, especially given that mass data are the most certain data element of WMPT. Therefore, it is important to collect mass data and to include it in WMPT. (S1s:29,32)

- BRS mass data cannot be imported into WMPT because it is from a mainframe system. The next version of the tool should allow entry of mass data from mainframes. (S1s:31)

- The mass data would be impossible to obtain on a national scale. Many states do not have the authority to collect it. If it were possible to obtain the data, it might be some of the highest quality data available. (S1i:36)

- The WMPT software includes a mass component which is intended to reflect "the amount of a chemical that is released or is potentially releasable to environmental media, and thus potentially available as a source of environmental exposure." User's Guide at B12. The Panels understand that several states intend to identify priorities for waste minimization and possible enforcement actions by combining the overall chemical rankings with this mass value. Thus, even low scoring chemicals, such as hydroquinone and isopropanol, could be targeted for waste reduction and, potentially, enforcement actions, simply because they have high mass values. The Panels strongly object to using a mass component to target low toxicity chemicals under a waste minimization program that allegedly focuses on the most PBT compounds. Over the past decade, many facilities have increased their usage of non-PBT chemicals, such as hydroquinone and isopropanol, precisely because they have committed to reducing usage of PBTs, and have aggressively sought environmentally preferable substitutes. Chemical Manufacturers Association (CMA) and the Panels support these efforts (CMA's PBT Policy Implementation Guidance, February 1996). EPA should encourage this kind of behavior. Indeed, EPA's Waste Minimization National Plan states that its goal is to reduce "the generation and subsequent release to the environment of the most persistent, bioaccumulative, and toxic chemicals in hazardous waste" Waste Minimization National Plan, p. I (November 16, 1994). EPA even describes the WMPT as promoting several "major shifts in concept," including "expand[ing] from reducing the volume of waste to reducing the toxicity of waste." Presentation of Donna Perla, EPA, on the WMPT, July 11, 1997. Yet the mass component the WMPT could have exactly the opposite effect. Non-PBT chemicals that are used in large quantities precisely because they are non-PBT could be considered higher priorities for waste minimization efforts than highly PBT chemicals, simply because of their use volume. Thus, the mass component could produce the unintended, and environmentally detrimental, result of focusing attention on reducing "less PBT" wastes while ignoring "more PBT" wastes. EPA, therefore, should remove the mass component from the WMPT, or at least not apply it to low ranking chemicals, to ensure that non-PBT

chemicals, such as hydroquinone and IPA, are not inappropriately targeted for reduction. (The Panels recognize that it is appropriate for a facility to consider the volume or mass of each waste when developing a site-specific waste minimization plan. However, it is not appropriate to consider volume on a national level in a way that causes low toxicity compounds to be inappropriately identified as high priority targets for waste reduction efforts.) (D26:ii,8,9,10; D16:i,12,13; D25:17,18,19)

8. Scoring Using "Bins"

a. Use of Binning vs. Continuous Scales

- There needs to be an emphasis on the use of the logarithmic scale used in the WMPT. There is a general misunderstanding about log units and so the difference in scores is not fully appreciated. This could be remedied by using graphics (i.e., not log-scale charts) that would demonstrate the difference in units. Most participants believe that the present scoring range for PBT is too narrow. Part of the problem is likely a misunderstanding of log units. If the 6-18 range is going to be continued, then it needs to be more explicit that it is a log scale. For instance, the report should at least label the mass scores as being a log scale. (P1:10, 40)

- The use of a single score approach reflects greater certainty than actually exists in the underlying data. This national scoring application differs from site-by-site risk evaluations where the actual and potential receptors (human and ecological) can be identified and evaluated using the appropriate human or ecological toxicity criteria (D49:28)

- Quantitative scoring is unnecessary for prioritizing chemicals for implementation of the National Plan. It is equally valuable to use a qualitative ranking scheme (i.e., high, medium, and low) that provides a relative comparison of the chemicals evaluated, while recognizing the limitations and uncertainty associated with the method. To better address the goal of the 1994 Plan, this quantitative ranking should be applied to a subset of the PCL chemicals, with the bulk of the chemicals on the existing list remaining unranked. (D67:2,3)

- The Pulp Chemicals Association favors the use of continuous scoring scales rather than the crude 1 2 3 binning approach. The fencelines of each of the bins have been set to contain at least two orders of magnitude. Thus it is possible for a chemical that is low in the ranges in all six categories (human PBT and Eco PBT) to have the same WMPT score as a chemical that rates high in the same ranges in all six categories. The difference in risk could be as much as 10^6. A continuous scale system would eliminate this disparity. Alternatively EPA could use more bins (e.g. 10 or 12). (D60:3)

- Consider using a continuous, possibly numeric, data quality hierarchy tier (or scale) to allow for better resolution and to ensure that best quality data are always used in scoring. (S1s:32)

- The scoring system of fencelines and bins does not adequately differentiate the chemicals that are of most concern and that score low at a facility level. As currently structured, WMPT gives a false sense of security because most of these chemicals will be ranked low. Therefore, a facility manger will assume that they will not have to make any efforts to reduce waste because the chemicals it uses are ranked low on EPA's list. (S1e:19)

- The use of the binning approach causes the compression of data covering multiple orders of magnitude, thereby ignoring significant differences in data values and increasing the uncertainty of the PBT score. This may be a reasonable approach given that a significant portion of the data sets used within the WMPT use the three-bin approach and some of those data are CBI classified. For the purposes of establishing a "PBT" chemical list, cut-off values should be set conservatively and a "border analysis" should be conducted on chemicals falling just above or just below the threshold score. (E1:7,11)

b. Number of Bins

- The scores do not allow enough range. Cancer potencies and reference doses range over several orders of magnitude, yet the score for these parameters goes only from 1-3. For a mid-range exposure score of 4, for example, the human health risk potential can only go from 5 to 7. The same is true on the exposure side and for ecological effects. (P1:A-5)

- Some modifications would greatly improve the tool's value. First, the ranking range from 6-18 is too narrow and may actually mask the significance of the differences between a chemical ranked 6 versus and chemical ranked 18. Particularly for the lay person, a broader range from least hazardous to most hazardous would be beneficial. While the mass weighted ranking is one of the most powerful functions of the tool, the logarithmic scale used for mass values again is likely to mask the significance of the differences between respective rankings of two or more chemicals, particularly for the lay person. (P1: A-8)

- A chemical should receive a score of zero for any individual element, which would demonstrate that it has low toxicity, is non-persistent, or is non-bioaccumulative. Similarly, a chemical could receive an overall score of zero, demonstrating that it is non-PBT. By utilizing either one of these approaches, EPA could ensure that non-PBT, low-ranked chemicals such as IPA are not perceived as PBTs simply as a result of their inclusion on the PCL. (D16:3,14)

- WMPT scoring methodology is misleading in that it does not include a score reflecting a zero level of bioaccumulation, persistence or toxicity. Thus, the mere inclusion of a chemical on the list misleadingly suggests that the chemical poses a risk. With all other scores being equal, a non-toxic chemical with greater mass could receive a higher prioritization than a toxic chemical of lower mass. Such a result will lead to inaccurate perceptions of the risk associated with a chemical and inappropriate risk management decisions. (D49: 17)

- Any chemical on the list that has a rating may give the public the impression that all of the chemicals on the list are of concern. Therefore, a "0" ranking needs to be incorporated into the rating scheme to avoid the misconception that a chemical is "bad" simply because it has a score based on PBT characteristics. (D75:17)

- We believe the WMPT methodology is unduly arbitrary and significantly flawed, particularly as it applies to metals. We do not understand, for example, why chemicals should be scored at all for characteristics (like persistence or bioaccumulation) that they do not exhibit, i.e., why there is no score of zero. (D56:3)

- The 1, 2, 3 scoring system is very broad. For example, sodium benzoate and toluene have the exact same scoring. Perhaps a larger scale would better prioritize chemicals. (D71:1)

- The scoring system has several inherent flaws. We are concerned with the use of the scoring system with 1, 2, and 3 as the only possible scores. Because the score of zero is not allowed, this gives the false perception that even a chemical that EPA recognizes has no hazard in a particular category has enough hazard to warrant a "1." We believe that this system leads to inflated scores for those chemicals with essentially no hazards in a particular category, and thus skews the ultimate overall scores. (D76:4,5)

- All of the ketones are examples of compounds that should and would drop out of the WMPT program if EPA were to adopt Chemical Manufacturer's Association's recommendation for zero-based scoring. (D17:3)

- This problem with EPA's "binning" approach could be alleviated by creating many more bins, so that the impact of exceeding the upper border of one bin is not so severe. (D17:19)

- Given that there are many intended users of WMPT, it is important that WMPT be completely transparent and its output simple to interpret and use. A preliminary screening tool should allow interested parties to direct their immediate attention to the substances that pose the most and least risk (or that possess the highest and lowest intrinsic hazard). Then, risk managers can direct their activities towards decreasing, substituting, or encouraging the use of products and processes to provide an overall "cleaner" effluent stream. Therefore, chemicals within each "rank" should be of approximately equal risk. Within the constraints imposed on any system that is an effective continuum of toxicity and exposure, there should be the capacity to distinguish between "ranks." WMPT does not have this capacity. (D31:9,10)

- The scoring range of the WMPT, which was derived from the Use Clusters Scoring System (UCSS), should be enlarged. The Science Advisory Board (SAB) criticized EPA's use of a three tier scoring system for the UCSS as being too general and subjective, and urged it to create a scoring order. (D49:18)

- The model should make finer distinctions between chemical properties than a 1-3 rating. Using only three possible ratings results in the same score for chemicals with very different properties. More gradations or a method of continuously quantifying the risks is recommended. (D31:cover2)

- More meaningful distinctions between chemicals are needed; the WMPT should not utilize such broad chemical categories. (D27:77)

- The limitations defined in Section A.6 (p A-12) regarding the Scoring Approach used in the Tool are accurate and raise significant concerns about the scoring method and utility of the chemical rankings. However, the rationale for selecting only three "scores" (i.e., 1,2 or 3) for toxicity , persistence, and bioaccumulation parameters is unsubstantiated in the User's Guide. A hypothetical compound with an aquatic chronic toxicity (LC_{50}) of 99 ug/L is apparently scored as being 33% worse than another compound with a chronic toxicity of 100 ug/L. Further, the more toxic compound would be scored the same as an extremely toxic compound with an LC_{50} of 0.001 ug/L. (D30:7)

- EPA should revisit the scoring system and recognize the implications of starting a ranking scale at 1 rather than 0. (D33:2; D37A:iii; D38:1; D41:1)

- The range of scoring used for each element of the WMPT to score a chemical's human and environmental toxicity and exposure potential, based on persistence and bioaccumulation, is too narrow. The overall score of a chemical, using this narrow range, will be insufficient to develop a prioritized list of thousands of chemicals. (D35:4)

- Increasing the scoring range from low to high risk will allow further differentiation among the high risk chemicals. The commenter suggests a scoring system using a broader scale of 1 to 5. (D35:4)

- The three point scoring system used by the WMPT is far too narrow to develop a reliable risk-based ranking of nearly 900 chemicals even at a screening level. EPA did not address the Science Advisory Board's (SAB's) criticism of the three tier ranking system used for the UCSS. SAB described the UCSS ranking system as too general and subjective, and urged EPA to create a ranking order. Nonetheless, the WMPT relies on a simple 1 to 3 ranking scheme to score the relative toxicity, persistence and bioaccumulation of nearly 900 individual, unrelated chemicals. The commenter believes that such a crude scoring approach is not adequate to rank a large number of unrelated chemicals, even as a screening tool. Although it may be impractical and undesirable to individually rank each chemical, the commenter supports the inclusion of additional ranking tiers in the WMPT. (D20:i,3,6)

- Small-order binning (i.e., providing only a small number of "bins" into which chemicals can be sorted) has the effect of "lumping" rather than splitting," where lumping can be described as a sorting activity that puts materials together based on their similarities rather than their differences. "Splitting," on the other hand, is a sorting activity

in which differences receive more attention than similarities. The net effect is that there is little certainty that rankings are meaningful for purposes of demonstrating that chemicals with the highest scores are likely to pose a greater hazard than those with the lowest scores. There is very little confidence that chemicals whose scores differ by one, two, or three ranks do in fact have higher or lower inherent hazards. Even in an initial screen, it would be better to have more degrees of separation in order to more effectively direct waste minimizing activities. (D29:3,4; D31:10,11)

- Insufficient separation of potential toxicants within classes can be found at various points within the PCL. Dioxin (acutely toxic) and copper (chronically toxic) are very different chemicals which pose very different risks to humans and the environment. However, WMPT assigns both an overall score of 13, making it difficult for a manager to make decisions about intra-rank chemicals. Similarly, the degree of risk posed by 2,3,7,8-TCDD versus PCBs or toxaphene is not adequately represented in WMPT. These chemical bound the 18 rank of the PCL, which should encompass two orders of magnitude of toxicity ranks. However, there are, in fact, four to five orders of magnitude difference between toxicity measures (i.e., cancer potency) for the chemical at the top of the list (i.e., 2,3,7,8-TCDD) and at the bottom of the list (i.e., PCBs or toxaphene). (D29:5; D31:12)

- We oppose a single-scoring system; however, if a single-scoring system is to be used in WMPT, more levels of separation should be provided so that clearer distinctions among chemicals can be made. (D31:14,15)

- The WMPT uses too few bins to meaningfully distinguish chemicals. (D18:19; D21:5)

- The range of scoring (1 to 3) used for each element intended to represent a chemical's toxicity or exposure potential is too narrow to develop an accurate relative risk-based scoring of almost 900 different chemical substances. At a minimum EPA should broaden the range of scoring so the scores can distinguish chemicals that would otherwise be ranked equally despite their vastly different risks. (D49:3, 18)

- In some instances, EPA should either eliminate the use of the data or add an additional scoring hierarchy of "very low." Very low or no confidence indications should be placed on scoring that are derived in the absence of data. (D49:22)

- The use of the highest score among competing indices and a 1, 2, 3 rating is not a very precise way of distinguishing between chemicals. Although EPA states that WMPT is designed to differentiate between chemicals that differ by two orders of magnitude, the score of 2 covers two orders of magnitude, but the scores of 1 and 3 capture the rest of the data. More gradations or a method of continuously quantifying the risks are recommended. The use of zero for the lowest tier also is recommended, so that something totally benign would not receive a positive score. (D32: 5)

- The high, medium, and low category scoring system is too blunt to provide meaningful rankings for hundreds of individual, unrelated chemicals. Individual ranks should not be established for each chemical, but more than three ranks are needed. (D27:57-58)

- The scores do not allow for a wide enough range, especially in regard to toxicity scoring. Cancer potencies and reference doses range over several orders of magnitude, yet are fit into just three bins. (D8:2)

- EPA could create a "zero" score for chemicals that have low toxicity, low persistence, or low bioaccumulation. A chemical could then receive an overall score of zero, demonstrating that it is non-PBT. Acetone is an example of a compound that would drop out of the WMPT program if EPA were to adopt zero-based scoring. (D14:3,14)

- The use of three bins does not allow for adequate differentiation/ discrimination between chemicals. In particular, WMPT does not distinguish between chemicals receiving lower scores. It appears as if there are too many

chemicals in the first and second bins. For example, the chemicals on the PCL with a score of 18 cover only half a page, while chemicals with a chemical score of 7 cover 3 pages and those with a score of 6 cover 2 pages. Therefore, it appears as if WMPT is designed to only identify those chemicals that are of the highest concern (e.g. those chemicals with a score of 17 or 18), while other chemicals are lumped together. The binning approach in the current system really has two categories; a "larger than" category and a "smaller than" category. There is also a middle category that spans a range of two orders of magnitude. Increasing the number of bins will add more distinction to the top and bottom categories and make the middle categories smaller by having it range only one order of magnitude. (S1e:18,19)

- Increase the number of bins to decrease the order of magnitude that exists within the various categories. Consider adding bins to the top and bottom categories. (S1e:19)

- The range of scores (from 6 to 18), which covers 12 orders of magnitude, is sufficient for differentiation between chemicals. Even greater differentiation between scores is possible when mass data are added to the algorithm. (S1s:25)

- It is impossible to distinguish between chemicals within a bin. 55% of TRI chemicals receive scores of 6-9, and 31% are not scored. The concern is that the WMPT does not differentiate between the chemicals that are most likely to be of interest to manufacturers. In addition, WMPT gives a false sense of security because most of those chemicals will be ranked low. If there were more bins, it would be easier to distinguish between chemicals other than those at the very top of the priority list (i.e., the PCL). (S1e:39)

- Limiting the number of bins to three increases the uncertainty associated with PBT scores. Increasing the number of bins would decrease the variability of values within each bin, leading to more precise scoring. (E1:7)

- The scores do not appear to allow enough range. Cancer potencies and RfDs range over several orders of magnitude, yet the score for these parameters goes only from 1-3. (D55:3)

9. Addressing Uncertainty

a. Data Quality Needs to be More Transparent

- As the WMPT system is now constructed, there is no ability for a chemical manufacturer or community representative to access any of the original data used in calculating chemical scores. There is no ability to evaluate the validity or comprehensiveness of this data; the system as a whole is not in any way transparent or publicly accessible in a way that the modern standards of public accountability require. This lack of transparency critically impairs the ability of the software to function as a credible timely tool for citizen use. (D80:2)

- The WMPT should be refined to provide some type of quality rating for a chemical's score so that the user has an indication of the quality of the data that went into the score. (D77:2)

- Similarly, diisobutyl ketone was assigned an ecological toxicity score of 2, but no data was in the software to document the reason this score was assigned. Methyl propyl ketone also had no documented data in the WMPT, but it was assigned an ecological toxicity score of 1. It is unclear as to the rationale for the assignment of the scores. (D75:13-14)

- The source of the data and the methodologies that the WMPT utilizes to assign a score based on that data is not clear. (D75:13)

- The WMPT does not distinguish those values that are admittedly of questionable quality from those that are of higher quality. For instance, some of the data from the IRIS database were derived from studies that the database itself characterized as "low confidence." Yet the WMPT assigned a "high quality" rating to the data because they were obtained from the IRIS database. (D75:17)

- References need to be made available for each parameter scored. Industry may have studies that were not considered in the scoring process. (D71:1)

- Our ability to provide meaningful comments has been hindered somewhat by a noticeable lack of transparency in EPA's process for developing the WMPT. It is our understanding that individual companies have had difficulty identifying what data source(s) and their uses in the WMPT methodology for ranking their chemicals. This situation exists because of insufficient information in the docket on the sources of the data and explanation of the methodologies in the WMPT for ranking chemical wastes. The American Crop Protection Association believes that the Agency needs to correct this situation by opening the WMPT to further public scrutiny, including a Science Advisory Board review, after incorporating the inputs from this comment period. (D69:1,2,7)

- Other than the RfCs and RfDs found in the IRIS and HEAST databases referenced in Appendix C (Scoring Human and Ecological Toxicity), it is ambiguous as to what specific data were used to determine PBT scores and where they can be found. (D64:3)

- The methodology and databases also are not transparent in many respects. Interested parties cannot identify, and confirm the accuracy of, data elements on which the WMPT has relied. For example, information needs to be provided on the "low quality" human toxicity databases, the Graphic Exposure Modeling System (CLOGP Version 3.3, EPA 1981) measured LC_{50}/EC_{50} for most sensitive species, inconsistent values, the contractor reports behind the secondary chronic values. (D43:i,12-16)

- The waste minimization draft documents and software, together with the draft PCL assigning prioritization scores to chemicals, provide insufficient explanation of the manner in which the Agency has selected particular data for inclusion in the scoring program or how it has rejected other data. The result of the program is a list of chemicals

which have composite scores that may be interpreted as supporting waste minimization; yet the bases for those scores is unclear. (D68:4)

- While the User's Guide and System Documentation for the Tool provide lists of data sources, the Agency has not provided enough detailed data to enable the public to ascertain exactly which test results were used, why they were used, and why other results were ignored. EPA has also not explained how exposure information is used in the process. This is a serious flaw in the draft system. For each of the chlorobenzenes included in the draft PCL, there are several data points that can be used to estimate persistence, bioaccumulation and toxicity. It is unclear why EPA has used particular results to reach the proposed score. (D68:7)

- Additional information is available for the other listed chlorobenzenes, as well. It is important that the Agency specify which data were used in reaching the scores reported in the PCL. In that way, interested parties can determine whether the scores listed are reflective of the actual database. (D68:10)

- In addition to having an indicator of how EPA feels about the chemical data (high, medium, or low quality) it would be nice to have a reference of what the data is. (D58:1)

- If EPA could make the ranking easier to understand, it would help. For example, the human health rank of 2 for tetrafluoromethane is neither obvious nor explained. Perhaps if we could "view fencelines" for specific chemicals, it would help. (D58:1)

- The database underlying the tool should consist of scientifically sound, fundamental data points, and should exclude "prescored," manipulated, and extrapolated results derived from actual data. Any derivation to be applied to a data point to convert it into a "score" should be integral to the algorithm of the tool, rather than part of the database. This kind of approach allows consistent and uniform application of assumptions to all data points, and permits complete and easy correction when an assumption is found to be faulty or better modeled by a different assumption. (D64:3)

- Data quality and availability are both difficult issues. For use solely as a screening tool, there will be numerous instances where no data, or limited data, are available. In most cases, we will not possess information on NOELs, but we will have an acute lethal dose by inhalation, a mutagenicity screening test, or a structure analogy to infer relative toxicity about some new compound. It is not clear how the tool would accept and use these kinds of inputs. The alternative, however, which is to do nothing until data is available, is not an acceptable one, either for protecting the health of our employees or for preventing environmental harm. While we want to use the best data we have, as a practical matter, we will use whatever reasonable information we can pull together. In light of this, it would be especially helpful if the WMPT allowed association of notes or comments with each data field, so it would be clear which fields were based on testing, which on structures, which on other predictive models, etc. (D64:3,4)

- EPA ranked the ketones for human health toxicity based on outdated information or using non-transparent data sources. Even if the overall score is correct, where the WMPT contains inaccurate or outdated toxicity data, those data will be disseminated to the public and create a misleading impression of the available data and overall toxicity of chemicals. Accordingly, it is critical that the data underlying the rankings be accurate, transparent and up-to-date. (D17:i,3-4)

- The basis for the "TSCA Submissions Scores," which were identified for five ketones, cannot be determined using publicly available information. The TRIAGE database, which EPA cites as its source for these scores, provides no explanation as to how EPA evaluated the TSCA Section 8(e) submissions to determine the rankings for individual chemicals. The commenter does not believe that any ketones warrant a human health toxicity score of 2

based on TSCA Section 8(e) submissions, but absent additional information in the record, the commenter is simply unable to offer any specific comments on the Agency's analysis. (D17:i,10-12)

- The basis for the "Human Toxicity Rankings" used to set scores for seven ketones cannot be determined from the information provided by EPA. (D17:ii,12)

- EPA has not provided adequate background information to permit meaningful review of the application of the persistence criteria to individual compounds. Indeed, the identified ketones received very close scores in both the BIODEG survey and the Fast BIODEG Probability, yet some ketones received a persistence score of two while others received a one. (D17:ii,17-19)

- Users cannot gauge the accuracy of WMPT's rankings, whose manner of assessment is not revealed in the software, nor seek the correction of these rankings. (D24:2)

- The data quality hierarchy structure should be consistent for all data elements (i.e., high, medium, and low versus highest, high, medium, low, and lowest). (S1s:32)

- It is not clear (1) who selected the data elements included in the WMPT database and why they were selected, (2) why the data quality hierarchy was structured as it was, and (3) what the definitions are of individual data elements. (T4:1)

- It may make sense to present in the WMPT outputs the percentages of data that are default data (i.e., from models), low quality data, medium quality data, and high quality data. (S1s:24)

- Monte Carlo simulations could be used to quantify uncertainties of scores. (S1s:24)

- EPA should be consistent in evaluating and applying underlying factors to adjust WMPT scores. When the WMPT considers multiple factors, it is inconsistent in applying the data to the scores. (D36:4)

- It is impossible to assess the validity of the score assigned to a particular chemical when the basis of the score is not provided. This is a critical shortcoming, rendering EPA's scores virtually useless. (D44:3-4; D44:5)

- The WMPT needs to be modified to recognize that data within a given database will vary in quality, depending upon the sources of information for that database. While EPA has acknowledged in the past that individual data sets are outdated, erroneous, or based on suspect research, these data quality concerns are not carried over into the WMPT. (D33:2)

- The scientific basis for the scores assigned to an individual chemical by the WMPT is unclear because there is no reference to the source for the chemical-specific values in the database. (D35:1-2)

- The source of data used in the scoring of persistence, bioaccumulation, and human/environmental toxicity is not clear. EPA should provide references or citations for all sources of chemical-specific values so that data may be checked for accuracy by the manufacturers. (D35:4; D36:6)

- There is no way of knowing how or why the WMPT assigns specific scores, and therefore impossible to correct any errors in the scoring. For example, propylene glycol ethyl ether acetate is assigned a score of 2 for human health toxicity, but even after examining the score's underlying data and the User's Guide it is not clear how or why EPA assigned a score of 2 rather than 1 or 3. (D46:2)

- The deviation procedure and data used are not transparent or evident, so there is no scientifically justified method to modify the list to reflect new information or better understanding. (D30:2)

- In the case of aryl phosphates, it is not possible to provide meaningful comment on the proposed chemical rankings, because even the most basic information is not provided in the docket. (D21:5-6)

- What specific studies were used to determine the chemical rankings of the aryl phosphates for which Chemical Data Summaries have been prepared? (D21:5)

- What was the basis (criteria) for choosing the specific studies used by EPA to assign rankings? For example, were only peer reviewed studies used? (D21:5)

- Was full GLP (Good Laboratory Practices) compliance a criteria for selecting the studies from which data were used in the ranking process? (D21:5)

- What are the criteria used by EPA for ranking data as being either of high, medium, or low quality? (D21:6)

- EPA should withdraw any rankings from the WMPT that are not based on transparent data sources that are readily accessible for public comment. EPA has ranked several oxo process chemicals and aryl phosphates for human toxicity based on non-transparent data sources. The bases for the TSCA Submission Scores, the Human Health SAT Rankings, and the Human Toxicity Rankings cannot be determined using the information provided by EPA. It is entirely inappropriate to rank the human health toxicity of aryl phosphates or oxo process chemicals when information is outdated or the basis for these rankings cannot be determined, evaluated or critiqued. (D21:i; D25: i,20)

- The quality of the data may be even poorer than is evident from the information in the WMPT due to the lack of transparency concerning the WMPT. For example, the ecological toxicity score for Octamethylcyclotetrasiloxane (OMCTS) is 3, despite its low risk. Because the score assigned to OMCTS was based on "prescored chronic data" without any explanation or identification of underlying data, this score cannot be fully commented on. (D49:25)

- Underlying data and documentation for underlying methodologies are not available and no public documentation exists as to how the draft PCL scoring were assigned. Without such information, stakeholders lack the ability to evaluate fully the validity of the underlying assumptions used in the WMPT to rank a particular chemical. (D49:25-26)

- Sources of data should be identified and made available to allow interested stakeholders an opportunity to verify their scientific validity, to comment meaningfully and to help EPA correct any inaccuracies. (D49:4)

- The current algorithm and use of data quality descriptors has no means for weighting the data quality into the scores assigned. Only 21% of the chemicals on the PCL had high quality aquatic toxicity data and 58% had high quality human toxicity data. There is no listing in the WMPT documentation of the fraction of chemicals that have high quality data for P or B. (D32:8)

- The underlying sources of the data and methodologies used for chemicals in the WMPT are not clear, preventing a full evaluation of the WMPT by interested parties. [More specific examples of this lack of transparency are listed here as separate bullets.] (D27:ii, 51)

- EPA has not provided in the docket explanations of the source or method of computation of "pre-scored acute data" or "pre-scored chronic data" for various chemicals. (D27:51-52)

- Some sources do not contain the WMPT cited values for certain chemicals (e.g., neither IRIS or HEAST contains an RfD for cresols). (D27:52)

- EPA has failed to provide significant information on ranking methodologies (e.g., one-third of the health scores are based on unexplained toxicity databases, and there is no supporting documentation provided on rankings obtained using CLOGP, BIODEG, and IRIS). (D27:53-54)

- Some indication of how much "faith" to put in the chemical scores based on the quality of data that determined the score would be helpful. Adding to the Chemical Data Summary report the data quality level of the data used to develop each subfactor score is one possibility. (T3:1)

- The system should provide an explanation of the sources or significance of the values given for the priority criteria for the six factors. They are often listed as 0.1 or 0.001 and shown as the key reason for a risk value. However, there is no explanation about where the number came from or what it means relatively or in comparison to others. (T5:3)

- It seems impossible to separate the data questions from the policy questions. Questions about how the data should be used and how the list should be used depend somewhat on the quality of the data. Should the lower quality data be presented differently than the higher quality data? It might be worthwhile to put some algorithm into the WMPT so that a chemical is ranked and there is an associated estimate of the uncertainty of the rank. It might, however, make the tool excessively complicated. (S1:6)

- The scores should be weighted by the quality of the data. Alternatively, chemicals could have a hazard score derived from the WMPT and a "certainty" score based on the quality of the data. The SCRAM model takes account of uncertainty by assigning values for certainty/quality of data. Companies would be less concerned about a priority list that considered data quality. In addition, the "certainty" score would help a company choose between chemicals with the same or similar hazard scores. It might also point out which chemicals should be targeted for research. Each of the P, B, and T scores would have associated "certainty" numbers assigned to them. However, the question then arises as to whether a higher priority should be given to a chemical with a high hazard ranking and low uncertainty or a low hazard ranking with high certainty. (S1i:9)

- It may make sense to create two lists for human hazard—one with high quality data and one with lower quality data. Two additional similarly constructed lists would be developed for ecological hazard. In order to prioritize chemicals for targeting, a decision criterion would need to be developed. (See table in Section I.A.1.a) For the priority ranking, the score associated with the highest quality data would be chosen first. The decision about cut-off points between high quality data and low quality data could be made by a science policy group. It might make sense to have three data bins for data quality—high, medium and low. If both scores were based on low quality data, the chemical should not be ranked. (S1i:9,10)

- It is difficult to track the source of data used in the model. EPA should show the citation for each data element to make the tool more transparent. (S1i:12)

- There appears to be a mix of very strong and weak data used in the WMPT system. The system should include some measurement of the level of uncertainty associated with the quality of data, and the true quality of the available data should be integrated into the overall score. For example, in risk management and risk assessment, there is a regret function that tells the user to pay closer attention to a particular chemical for which the potential hazards may have been underestimated. The regret function is a heavy weighting of the probability that a chemical is hazardous. Similarly, the SCRAM model has a chemical score and an uncertainty score to indicate the quality of data. While it is extremely difficult and expensive to make this type of modification, EPA should at least assess

the information for a selection of chemicals that indicate the quality of data. Additionally, EPA should consider developing a flag or data quality indicator that indicates that a score is based on poor quality data. (S1e:17,18)

- Given the variances in quality of the underlying data, consider developing a flag to identify whether the scores are based on very poor quality data. (S1e:18)

- When high quality data are not available, use a conservative scoring technique as a precautionary measure and to encourage the development of higher quality data. (S1e:18)

- If a method is identified to score these data, flag them to indicate the quality of data. (S1e:20)

- Because the tool is an EPA product, users will assume that it is based on defensible science, which is not the case with the inclusion of low quality data elements. Therefore, it is important to make the distinction between the different types of "performance standards" of science commonly used in risk assessments (i.e., planning science, regulatory science, and pure (defensible) science) and to indicate in the documentation that regulatory science performance standards are used for WMPT (i.e., when data from pure science are available, they are used. If data from pure science are not available, other data, such as that from models, are used. Any data that does not result from pure science will be validated where required). (S1s:24)

- Facilities are less likely to use WMPT if uncertainty and other complexities are added; uncertainty is not very important to the facility users. Also, in keeping with the risk assessment paradigm, risk assessments do not include any information on default values used. (S1s:25)

- The data quality hierarchy structure should be consistent for all data elements (i.e., high, medium, and low versus highest, high, medium, low, and lowest). (S1s:30,39)

- Do not add (numeric) uncertainty scores to overall scores, and do not (numerically) adjust scores for uncertainty. Instead, more clearly state up front in the user's guide the uncertainty limitations associated with chemical scores. Encourage users to view the underlying data and to take data quality into account when making real world decisions. (S1s:24,32)

- Users should be aware of the quality of the data used in the tool for the chemicals of interest to them. (S1i,e,s:37)

- WMPT does not attempt to quantify uncertainty inherent within the data used in the tool or the ways in which the data are used to calculate PBT scores. Recognizing that the WMPT data quality hierarchy is based, in part, on the uncertainty within the data sets, the lack of uncertainty quantification does not pose a significant problem providing that (1) this is clearly stated when discussing the limitations of WMPT, (2) the WMPT threshold score is conservatively set to address the inherent uncertainty within the tool, and (3) once a WMPT threshold score is established for the purposes of selecting "PBT" chemicals, a "border analysis" is performed to identify and add to the list those chemicals that fall just below the threshold as a result of just missing high risk designations in multiple subfactor areas. (E1:8)

- If possible, some type of quality rating for a chemical score should be provided. (D55:cover2)

- The tool should have the confidence statements associated with outputs such that the user can judge the strength of the outputs. (D55:1)

- The user should be able to identify the quality of the data on which the screening for a particular chemical is based. In addition, the user should be able to distinguish between chemicals that are not ranked because they are not considered toxic from those that are not ranked because there is inadequate data. (D55:2)

- The risk ranking system adopted by the WMPT fails to follow Administrator Browner' s directive regarding risk communication, which stresses the adoption of transparency in decision making and clarity in communication. (D40:8)

b. Priority Among Data Elements in Same Data Quality Tier

- Chemicals with well-defined PBT profiles are penalized in the WMPT. This occurs because EPA typically uses the highest PBT score when more than one data element is available, leading to higher scores for well-tested chemicals. The WMPT's approach to toxicity uses only a single quantitative measure derived from databases of varying size and quality. This approach is mechanical and inflexible, leaves little room for scientific judgment, produces inaccurate results, and may result in systematic bias in the rankings. For example, chemicals subject only to preliminary acute toxicity testing (rather than acute and chronic testing) will generally be assigned to a lower level of health concern in EPA's ranking system. (D27:ii, 13, 59-60)

- EPA should choose a scoring method that makes finer distinctions between values and incorporates the entire weight of evidence. The use of only the data element that results in the highest score may be good for the first tier list of concerns, but is not a good way to do the final prioritization because it does not include the entire weight of evidence. The SAB (An SAB Report: Improving the Use Cluster Scoring System, August 1995, p. 8) recommended that EPA develop a more quantitative score based on summing all the data indices, instead of just using the highest value. This is a way to bring in both acute and chronic toxicity issues and cancer and non-cancer endpoints instead of just using one worst-case data point. (D32:5)

- A priori use of the worst case data does not encourage the collection of better, more relevant data by users because the more data that are collected, the higher the chance that one study would produce high results even if it is due to experimental error or random variation. The weight-of-evidence approach takes all data into consideration appropriately. (D32:7)

- To the extent possible, EPA should use the most accurate peer-reviewed data when developing constituent scores. Measured data should take precedence over predicted data. (D29:cover2)

c. Other

- The data gaps that prevent the scoring and ranking of a large number of chemicals should be evaluated. Industry might discard those chemicals having low scores due to low quality data or no data. Therefore, a mechanism should be developed that indicates when there is no data for a particular score (e.g., flag chemicals that cannot be scored because of missing data). The absence of this data will provide incentive for industries to fill in these data gaps. (S1e:20)

10. Consistency with Other Efforts

a. Consistency with International Activities

- EPA criteria should conform with international initiatives and manage PBTS (a.k.a. persistent organic pollutants-POPS) underway through the United Nations Environment Programme, the United Nations Economic Commission for Europe, and the North American Free Trade Agreement on Sound Chemical Management. (D30:3)

- International workshops which have included official representation and participation from the EPA (e.g., OECD, 1995; Canada/EU, 1996) have recognized that persistence is not an appropriate measure for determining the hazard of metals. For example, Canada/EU (1996, p. 5) states: "Persistence should not be used in conjunction with toxicity and bioaccumulation in a holistic approach to hazard identification" and "There are no appropriate existing tests for the persistence of inorganic compounds relative to their hazard identification." (D50:5b)

- The OECD Working Group on the Harmonization of Classification and Labeling has also recognized that persistence is not applicable to metals such as zinc. Specifically, they accept the findings of OECD (I 995) and Canada/EU (I 996), and they are clear (OECD, 1996) that: "biodegradability [=persistence] is not an appropriate parameter for assessing metals." The US is represented and participates actively on that Working Group. (D50:5b)

- Finally, under the North American Free Trade Agreement (NAFTA) and as part of the North American Agreement on Environmental Cooperation (NAAEC), the North American Working Group on the Sound Management of Chemicals has established a 7-person (two from EPA) Task Force on Criteria. This Task Force has developed criteria for the selection of substances for risk reduction action (i.e., for similar purposes as the subject EPA document) and, in doing so, clearly state that persistence is not appropriate for the identification of hazard from metals. For example, under Resolution #955 they accept the findings of OECD (1995) and Canada/EU (1996), specifically referencing these. And, under Section 5 of their document, Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative, they state: "...[for] naturally-occurring substances like metals, and minerals... the potential for transformation to complexes or metallic species which are more or less bioavailable [must be considered]." Thus, EPA's Draft Prioritized Chemical List ignores international consensus on persistence as an appropriate measure, consensus to which the United States and specifically the EPA have been party. (D50:5b)

- The proposed rankings for the aryl phosphates are at variance with chemical rankings recently prepared by the European Commission (EC) specifically to address risks to human health and the environment. The EC found aryl phosphates to have low hazard profiles, and to be in or near the lower half (lower concern) of the chemicals that were ranked. In contrast, all aryl phosphates ranked by EPA for the draft PCL were in the upper half (higher concern) of the chemicals ranked.

- The most disturbing aspect of the WMPT and PCL is the Agency's apparent disregard for the fact that OECD SIDS reviews have been conducted on numerous oxo process chemicals in partnership with EPA's Office of Pollution Prevention and Toxics—one of the two offices that sponsored the WMPT. In preparing OECD SIDS dossiers for several oxo process chemicals, the Agency specifically sought a partnership with the Panel's member companies to complete its agreed upon international commitment to the SIDS program. The information included in the SIDS dossiers was carefully analyzed by the Agency and other SIDS participants, yet was ignored in evaluating these chemicals under the WMPT. There should be coordination at EPA between persons evaluating substances in the OECD SIDS program and staff reviewing the same compounds under other Agency programs. The treatment of oxo process chemicals in this initiative present a compelling case in point of different Agency programs working at cross-purposes. (D25:i, 3-4)

- Extensive data exist on oxo process chemicals. The Panel prepared dossiers under the OECD SIDS program for ethyl acetate, butanol, isobutyraldehyde, butyraldehyde and propionaldehyde. These documents, which contain extensive data on the human health effects, ecological effects, persistence and bioaccumulation of the subject chemicals, were carefully reviewed, edited and approved by EPA. Despite the Panel's testing and outreach effort, these data are not reflected in the WMPT. Instead, the WMPT relies on outdated data and models whose applications cannot be determined from the record. (D25:ii, 13-14)

- The Panel strongly believes that the WMPT should consider the available data in ranking individual chemicals, and urges EPA to carefully review the attached SIDS dossiers, incorporating the most recent and reliable data into the WMPT and revising these chemical rankings as appropriate. (D25:14)

- The proposed use of model-derived BCF estimates rather than actual BCF data contradicts a number of regulatory initiatives outside the U.S., thus hindering global harmonization efforts related to the characterizations of BCF. (D29A:13)

- It is possible that the differing selection criteria or fencelines (e.g., bioaccumulation, long range transport) in WMPT and international treaty negotiations could result in different chemical priorities. While this may not be a substantive problem at present, it may warrant attention from the U.S. delegation to future international negotiations. (E1:8)

- Perhaps the most disturbing aspect of the Agency's proposal to put hydroquinone on the Draft PCL is the Agency's apparent disregard for the conclusions reached in the OECD SIDS review of hydroquinone. In completing the SIDS dossier, the Agency was commended by the other SIDS participants for the outstanding job that was done in compiling not only health and ecological effects data for hydroquinone, but also extensive exposure information. This information was carefully analyzed, and the Agency and other SIDS participants concluded that exposure to hydroquinone was well controlled and that further measures were not needed (SIDS Initial Assessment Report for Hydroquinone. CAS No. 000123-31-9). Hydroquinone is not alone in being prioritized in the proposed WMPT without regard to the conclusions reached under the SIDS program. Other high production volume chemicals have been put through the OECD SIDS program and are undergoing review for prioritization. When a chemical receives a "Low Concern and Priority for further work" classification at a SIAM (SIDS Initial Assessment Meeting), it should not be highlighted as a priority for waste minimization under another program. There should be coordination at EPA between persons evaluating substances in the OECD SIDS program and staff reviewing the same compounds under other Agency programs. There simply is no reason for having hydroquinone on a waste minimization list. (D26:i,7,8)

b. Consistency with Other Screening Tools

- The prioritized chemical lists for air contaminants are very different between the two databases used in the Santa Clara County study. Of the top ten chemicals, only Nickel and Toluene appear on both lists. Furthermore, the mass of these chemicals was very different between the two lists. These results demonstrate how dependent the WMPT results are on the data sources used. These results also highlight the need to use multiple data sources, when possible, in developing community priority lists. (P1:36)

- In 1995, EPA issued a final rule whose purpose was to control discharges which ultimately reached the Great Lakes, "to establish consistent, enforceable, long-term protection for fish and shellfish in the Great Lakes and their tributaries, as well as for the people and wildlife who consume them." 60 Fed. Reg. 15366 (March 23, 1995). Considering the need for consistent regulation of point source discharges, EPA evaluated various controls on toxic pollutants and established acute and chronic criteria to protect aquatic life from acute and chronic exposures to pollutants. While having a similar pollution minimization purpose, the Great Lakes Guidance appears to reach inconsistent conclusions with regard to several chemicals. All of the chlorobenzenes included in the PCL, for

example, are included in a list of "Pollutants that are not bioaccumulative chemicals of concern" in the Great Lakes Guidance. See 60 Fed. Reg. 15393. (D68:6)

- Much of the information in the software regarding IPBC, 3-idio-2-propynyl butyl carbamate, is in direct contradiction to other agency evaluations of the product, and greatly exaggerates the hazards of IPBC. EPA should utilize the data provided in the Re-registration Eligibility Document on IPBC to update the information provided in the software and to lower the scores assigned to IPBC. The current version of the software provides exaggerated and unsubstantiated risk scores for IPBC, which unfairly puts manufacturers of IPBC at a significant competitive disadvantage and limits the usefulness of the software generally. (D44:5)

- Review and correct the data to reflect decisions made by your sister offices. (D37A:i-ii)

- The WMPT does not consider the scientifically based EPA risk assessments done for product registration. All pesticides go through a rigorous review, based on scientific studies for human and environmental effects, by EPA prior to registration. (D36:ii)

- EPA should review registered pesticide scores with EPA registration information to ensure accurate scores are generated by the WMPT. High overall scores assigned to some registered pesticides (e.g., pendimethalin) by WMPT conflict with EPA registration assessments of pesticides. (D36:ii; D36:4-5)

- EPA should review data for 4-chlorobenzotriflouride (PCBTF) and correct the PCL for PCBTF to reflect the decisions made by OPPT's sister offices indicating that the substance is not persistent, bioaccumulative or toxic. (D37A:i)

- EPA's review of acetone in the WMPT is not consistent with previous EPA reviews as well as the reviews of other state and local regulatory agencies that expressly recognize that acetone poses a low concern for human health toxicity. (D14:3)

- EPA, as well as numerous state regulatory agencies, have reviewed the available toxicity information on acetone and concluded that it should not be regulated as a toxic or hazardous chemical. To be consistent with the Agency's previous analyses of this chemical, the WMPT should assign to acetone the lowest possible score for human health toxicity. (D14:7-9)

- Numerous regulatory agencies, including EPA, have recognized acetone's potentially significant role in pollution prevention (as a substitute for more hazardous materials). Assigning acetone the lowest human health toxicity score would be consistent with EPA and state pollution prevention strategies.(D14:9-10)

- Due to testing pursuant to a TSCA Section 4 Enforceable Consent Agreement, there is an extensive database available for phthalate esters. Additionally, there are extensive data available from voluntary testing, testing by EPA, NTP, and other agencies, and other published data sources. EPA has ignored these data when developing and updating the WMPT; to do so is contrary to good science and good policy. EPA should ensure that a mechanism (such as a sufficient comment period) is in place to enable the Agency to take advantage of these data. (D18:i, 2, 9-10, 11, 19)

- The WMPT scores for phthalates do not agree with decisions made in other EPA offices, such as actions under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 list and determinations under the Great Lakes Water Quality Initiative. The high scores in the WMPT are at variance with separate EPA findings in these other actions. Due to this inconsistency, phthalate esters should be removed from the WMPT. (D18:i-ia, 17, 18)

- EPA has co-sponsored extensive studies of several oxo process chemicals under TSCA section 4 enforceable consent agreements (ECAs), yet none of this information has been included. (D25:3)

- In contrast to the draft List, the Agency currently utilizes an actual list of chronic toxicities for chemicals present in hazardous wastes for which delisting is sought. *Docket Report on Health based Levels and Solubilities Used in the Evaluation of Delisting Petitions Submitted Under 40 CFR 6260.20 and 6260.22* (Science Applications International Corp., EPA Contract No. 68W20027, Dec. 1994). One would expect that chemicals with the same human-health score as zinc in the List would have similar health-based levels for delisting purposes. However, some chemicals with the same human-toxicity level as zinc in the List have health-based levels for delisting purposes orders of magnitude lower than zinc's health-based level. Thus, any prioritization of waste minimization based on the List is flawed in that the minimization will target the wrong substances. (Note: American Zinc Association does not concede that Zinc's health-based level of 10 mg/l is correct. In fact, American Zinc Association believes that number to be too conservative. Nevertheless, American Zinc Association uses this number for purposes of comparison.) (D50:2)

- The Panel has striven to ensure not only that all data produced from its studies are submitted to EPA, but also that the data are published in the peer-reviewed literature and that appropriate EPA staff are aware of the data. The Panel has completed neurotoxicity testing programs for isobutyl alcohol, butyl acetate, ethyl acetate and n-amyl acetate that were included in an enforceable consent agreement under TSCA Section 4. The results of this testing were previously provided to EPA. Of significant concern to the Oxo Process Panel is that after entering into a partnership with the Agency to evaluate the health and environmental effects of oxo process chemicals, and further conducting extensive and costly testing on these chemicals, the Agency has ignored all of this information in making its assessment of the oxo process chemicals in the WMPT. The Panel also repeatedly has presented the results of its studies in comments submitted to EPA on various program initiatives, such as the Hazardous Waste Identification Rule and Soil Screening Guidance. Despite the Panel's testing and outreach effort, these data are not reflected in the WMPT. Instead, the WMPT relies on outdated data and models whose applications cannot be determined from the record. (D25:14)

- High WMPT scores assigned to some pesticides conflict with EPA registrations of those pesticides under FIFRA. (D27:19)

- If the goal of the Waste Minimization National Plan is consistent with the "Goals 2005" document, then the objective of the National Waste Minimization Measurement List is to be forward-looking, which means that a broader perspective should be taken, and multi-media effects should be addressed. (T1:4)

- The Sector Indexing project, which might use many of the same inputs, should be considered by EPA. (S1:4)

- Other EPA programs focus on acute hazards. Concerns about acute hazard always take precedence in plant operations. Waste minimization naturally concentrates on longer term concerns such as chronic risk. EPA might consider looking for other tools which include acute risk. EPA should communicate to users that WMPT is focused on chronic hazards and that the most important chemicals to minimize or manage are those which pose acute risks. Some acutely toxic chemicals, such as cyanide, are low on the draft priority list yet are acutely toxic. (S1i:11)

- Certain chemicals that appear on priority lists generated by EPA program offices and others do not receive high overall PBT scores from WMPT. This does not necessarily call into question the validity of the WMPT chemical ranking because of the variety of selection criteria in use. However, this is important to consider during the further refinement of the tool. (E1:9,10)

- Discrepancies between the initial working list (draft PCL) generated by WMPT and other chemical lists of concern should be investigated to determine whether WMPT requires refinement and to identify additional criteria for selecting "PBT" chemicals. (E1:11)

- EPA already has a risk management program under TSCA. The Joint Use/Exposure Information Project voluntarily compiles information for exposure assessments feeding into the Risk Management (RM1/RM2) Process. The hydroquinone producers have voluntarily provided information to EPA under this project, and are awaiting EPA's completion of the RM review of hydroquinone. The Panel is particularly disturbed that EPA has not completed its RM reviews under TSCA, but instead has taken a totally different and unwarranted route to prioritize its risk management needs for hydroquinone. EPA's uncoordinated approach is a poor reward for the Panel's voluntary efforts to assist EPA's risk management activities under TSCA. (D26:8)

- OSW should continue and expand their efforts to work with other EPA programs to develop a prioritization tool that has value or is related to other program priorities and can help States screen for potential cross-media transfer problems. This is especially important in relation to air, since meeting Clean Air Act requirements is likely to be the focus of many companies' expenditures in the near future. (D55:cover2)

c. Other

- We believe that the draft waste minimization prioritization tool (WMPT) and Prioritized Chemical List (PCL) are flawed because they are inconsistent with the 1994 Plan's goal to reduce release of the highest priority PBT chemicals. (D67:1)

- If WMPT does include chemical mixtures at a later date, it should follow the chemical mixtures guidelines. (S1s:26)

11. Process for Maintaining and Improving Data in System

a. Conducting Quality Assurance for Data in System

- The science behind these rankings should be peer-reviewed. Although the Agency believes the *system* of ranking the persistence, bioaccumulation, and toxicity (cluster scoring system) of these chemicals has been peer-reviewed by EPA's Science Advisory Board (SAB), it would be appropriate to conduct a peer-review of the actual application of this system, and associated real-world impacts, as implemented in the waste minimization prioritization effort. (D57:2)

- The rough screening method adopted for the Tool and used to compile the Priority List is far too uncertain and imprecise for the Agency to suggest that major waste minimization decisions be based upon these tools, even on a "voluntary basis"; thus the WMPT and the Priority List should not be released until the approach is scientifically defensible. (D30:2)

- The Tool and the Priority List should be evaluated by the EPA Science Advisory Board because they (1) constitute policy/guidance of major impact, (2) establish a significant precedent, model or methodology, and (3) address a controversial issue. (D30:2)

- Because the "toxicity" factors used by the model are not normally or appropriately used in the risk assessment process, their use in the model may be problematic. It was recommended that EPA revisit the toxicity factors (e.g. IRIS, HEAST,. RQs, etc.) to ensure that they are suitable substitutes for each other. (S1:40)

- I think that the level of complexity of the tool does not allow for a simple one day in, provide comments, and move forward strategy. I would suggest that end-users, such as the states, be heavily involved in the development and "smell-testing" of the product. That is, EPA customers should be working model iterations and evaluating the "how and why" documentation as it is developed. This would reduce any surprises at the end of the process when no time or money may be available to fix any conceptual or algorithmic problems. (S1:40)

- The importance of discouraging further use of the WMPT is underscored by the questionable assumptions in some of its scoring methodology and the information errors in the database. MPA has not attempted to identify all the problems with the WMPT, but one significant flaw in the database, namely reliance on outdated data, is exemplified by the scoring of methyl methacrylate. (D62:2)

- Basic Acrylic Monomer Manufacturers, Inc. has reviewed the entries in the database for several acrylates and found errors that should not be distributed under the EPA imprimatur. If the Agency is—as we urge it not to do—to continue using the WMPT, it must implement a mechanism for correcting errors. Without such a mechanism, the Agency will be promoting inaccurate and incomplete data and thus doing a disservice to the public. (D63:3)

- The Agency should initiate a multi-stakeholder (e.g., scientists, engineers and risk assessors) scientific peer review of the technical integrity of the Tool, including the algorithm and assumptions used in chemical prioritization, the method employed in selecting chemicals and data used in the Tool, and the significance and reliability of the Priority List as a priority-setting mechanism. Distribution of the Tool should be discouraged until the peer review (perhaps in the form of a workshop) is complete and recommendations have been implemented. (D30:2)

- EPA has claimed in recent published statements that the Science Advisory Board (SAB) strongly supported the science which forms the basis of the WMPT. On review of these documents supplied by EPA, we find that SAB raised many pointed questions with respect to the simplistic analysis utilized by the WMPT. In the SAB analysis dated September 26, 1995, the authors stated that several enhancements are needed to improve the scoring of

chemicals and clusters, including the incorporation of additional data for the exposure portion of the scoring algorithm, a measure of the performance potential of chemicals, use of high quality, consistent data sources for ecological and health risks, consideration of pollution prevention alternatives, and use of a credibility check to ascertain reasonableness of UCSS outputs (EPA-SAB-EEC-95-017 P.2). The authors also stated that the current analysis does not address the "no" chemical alternative. These alternatives should be identified and listed on the cluster for each use, recognizing that substitutes are not always the best means for pollution prevention, and often only shift or delay the problems. For example, often the substitutes may cause other problems, trading a human health exposure of an aquatic toxicity problem (EPA-SAB-EEC-95-017 P. 14). Whenever color pigments are substituted in product applications, compromises are made in some characteristics, such as weatherability, color, dispersability, and strength. These compromises can impact the useful life of the products in the marketplace. To encourage substitution without sufficient analysis using a Software algorithm is not a prudent strategy or use of resources. With respect to use cluster analysis, the SAB also recommended that a review and analysis of the model output to assure that it is reasonable and credible, including affected industries (EPA-SAB-EEC 95-017. P. 15). With respect to the Software which has grown out of the cluster analysis, we strongly concur that additional work on this analysis is warranted prior to publications. (D12:5)

- WMPT should not place Agency-reviewed data above other valid data sources. At a minimum, WMPT values should be subject to external peer review and should remain flexible so as to permit revision of relative ranking if compelling scientific data supports a change. (D32:1)

- In light of the certainty that the WMPT will serve as the basis for initiatives by state governments, environmental groups and industry, it is essential that the chemical rankings be based on the best available data. To be sure that ranking and priorities based on the WMPT are meaningful and accurate, the WMPT and PCL must not be based on poor quality, incomplete or non-public data. (D19:15; D20:21)

- EPA should incorporate all high quality data referenced by the SAB as well as by commenters on the WMPT. (D27:76)

- As it has acknowledged, EPA has not reviewed the quality or validity of each value entered into the WMPT. The WMPT should not be distributed until EPA has reviewed the data and commenters have been allowed sufficient time to examine and comment on the WMPT as well. (D18:11)

- Public interest is not served when EPA uses outdated and inaccurate information about chemicals to evaluate hazards of chemicals or establish waste minimization priorities (e.g., acetone). (D14:7)

- The databases used in the WMPT need to be updated and peer reviewed before being used for any EPA program. (D34:4; D34:6)

- There were too many discrepancies in the WMPT database and the literature available to set the proper parameters. (D34:4)

- EPA should correct and update all data used in the tool so that a more accurate ranking is produced. (D36:6)

- The Software has been released to the public prematurely without sufficient peer review form industry and risk experts with specialized knowledge concerning the chemical ranked in this initial listing. (D12:2)

- The WMPT incorporates outdated, incorrect, and/or unreviewable data. (D21:5)

- Was the final product of the WMPT project peer reviewed?

- The validation of the WMPT model should occur before the Agency finalizes and applies the WMPT. The example of Octamethylcyclotetrasiloxane (OMCTS) demonstrates the inaccuracies of the WMPT exposure model. OMCTS received a high exposure scoring on the draft PCL, despite the existence of evidence indicating low exposure to aquatic organisms. Such validation can easily be accomplished by comparing predicted exposure scoring with ranked monitoring data from selected chemicals where environmental concentrations have been well characterized. Such validation is critical to ensure that the scoring are accurate. (D49:25, 26)

- The test data used in the evaluations are not screened adequately for quality. The data comes from a variety of sources, many that have limitations which could disqualify them. A panel of outside experts should evaluate the final rankings recommended by the SAB (An SAB Report: Improving the Use Cluster Scoring System, August 1995, p.15) to ensure they are consistent with waste minimization goals. (D32:3)

- Any proposed tool must be based on sound science and must be subject to third-party peer review. (D54:4)

- The WMPT does not provide an adequate mechanism for ensuring data quality; such a mechanism is an absolute necessity in the WMPT. A data quality factor should be developed and noted in the final score for PBT values. The WMPT should include a "reality check" to validate outcomes of the tool; this reality check should allow for the involvement of the industrial users of the tool. (D27:ii, 56-57, 77)

- The WMPT uses erroneous, outdated, inaccurate, and incomplete data, even where better data are available. (D27:ii)

- The WMPT fails to take into account differences in data quality when ranking chemicals. (D27:ii)

- The WMPT relies predominantly on preexisting EPA databases; many of these are outdated, flawed, and/or not peer reviewed or checked for quality control. (D27:14-15)

- EPA should assess the quality of the data used in the WMPT rather than relying on an overall rating for the value type (D18:35).

- The WMPT ranking scheme incorporates information from databases where much of the toxicity information (e.g., RfC, RfD, RQ, RQPF, and Cancer Potency (Q*)) were collated, but not peer reviewed. Some of the data are not even accepted agency-wide by EPA (e.g., the values in the HEAST database). Therefore, these data may not be scientifically sound. In addition, these databases often contain outdated information. EPA should undertake a rigorous peer review of these data before applying them in the WMPT. (D29A:7)

- More information needs to be included in the WMPT database. (S1s:31)

- Tools such as the WMPT and the draft PCL will only be as good as the underlying assumptions and chemical specific data on which the Agency relies. It is critical that the most accurate and reliable health hazard information be used. Accordingly, if EPA is going to rely on the IRIS database as a starting point for the WMPT, or any other Agency initiative, EPA must commit the necessary resources to maintain a current database. (D16:5)

- Cement Kiln Recycling Coalition urges EPA to ensure that any efforts to prioritize or rank wastes for minimization purposes be based on sound science and current information. The use of any outdated data to determine the toxicity portion of the chemicals on the PCL would be wholly inappropriate. (D57:2)

b. Process for Challenging and Revising Data in System

- We strongly suggest that EPA submit the tool to the Science Advisory Board for review, since they could provide an independent review of the risk assessment methodology underlying the computer program. (D79:1)

- One of Eastman's recommendations to the Agency is to obtain an immediate Science Advisory Board (SAB) review of the WMPT. (D75:3)

- As noted in the Federal Register notice and the introduction to the WMPT and PCL, the 1994 Waste Minimization National Plan calls for the voluntary reduction of releases of the most persistent, bioaccumulative, and toxic chemicals. The WMPT and PCL, on the other hand, attempt to rank all of the chemicals for which the Agency has complete data. While evaluating the 879 chemicals in the PCL may be a useful starting point for developing the focused effort outlined in the Plan, the rankings only serve to distract public and industry attention from the goal of the Plan. The draft WMPT (and the resulting PCL), once perfected, will be very useful in creating a National Waste Minimization Measurement List of a small number of priority PBT chemicals. It is important and appropriate, therefore, that the WMPT and PCL be subject to rigorous review, but only in the context of providing the basis for developing the short list of priority chemicals. The materials should not be distributed as standalone documents, particularly if the Agency maintains the quantitative scoring system. (D67:2)

- It is critical that the most accurate and reliable health hazard information be used in the WMPT. Accordingly, if EPA is going to rely on the IRIS database as a starting point for the WMPT, or any other Agency initiative, EPA must commit the necessary resources to maintain a current database. EPA's consistent failure to utilize up-to-date information undermines regulatory programs that rely on Agency databases, and results in inappropriate risk management decisions and misdirection of resources towards reducing the chemicals which in fact do not pose hazards to human health and the environment. (D17:14-15)

- One important consideration that EPA will need to address if the tool is going to have ongoing value and validity and be used by Wisconsin includes making a commitment to update and refine both the prioritization tool and the crosswalk. (D77:2)

- We hope that EPA makes it easy to update the software through the world-wide-web and makes updates compatible with prior versions and any related applications that states may develop. (D77:3)

- One of Eastman's recommendations to the Agency is to update the WMPT periodically, as new data become available. (D75:4)

- If the EPA is going to continue to rely on the IRIS database, and other similar databases, it is essential that the Agency commit the necessary resources to keep those databases updated with the best quality data. (D75:14)

- A primary concern regarding the data is that EPA has communicated no plans for keeping this data compilation updated. The chemical industry invests millions of dollars annually to conduct testing on products in commerce, submitting the data to the Agency as required. This tool will quickly become stale if a plan for adequate and timely updating is not developed and implemented. (D76:4)

- Oregon Department of Environmental Quality recommends that the EPA ensure that the model is updated regularly. (D65:2)

- We were glad to see that the tool permits full editing of chemical data, allowing for input of new toxicity, persistence, or bioaccumulation data as it becomes available; this feature should be retained. However, some provision should be made to centrally share new information among users. EPA could maintain a repository for all

accumulated data submitted by users, perhaps on the EPA web server, where users could update their chemical database at their discretion. (D64:7)

- The WMPT has no mechanism to correct values already in the system, much less to update the tool. (D21:5)

- EPA has refused to establish a process to review and incorporate new data. The reliance on out-dated and incomplete data raises serious questions regarding the credibility and utility of the tool. (D20:14)

- At the least, processes must be established that allow for correcting and updating chemical data in the WMPT prior to use and allowing for case-by-case assessment of data scores and rankings. EPA should use current and best available data. (D27:73, 77)

- If EPA is going to rely on the IRIS database as a starting point for the WMPT, EPA must commit the necessary resources to maintain a current database. In the case of acetone, the Agency has merely perpetuated the errors in IRIS in the WMPT. Hopefully the recently implemented pilot program to improve the process of including information in the IRIS database will be successful. (D14:6)

- EPA should create a mechanism, such as an independent scientific review panel, whereby the data in the WMPT can be corrected or updated. (D14:7)

- As additional studies are conducted under an ECA over the next several years, it is important that EPA incorporate the results of the studies in the WMPT. Indeed, it would be unreasonable (and irresponsible) for EPA to require additional testing and then fail to incorporate the results of that testing in the WMPT. (D21:3-4)

- It is inappropriate for EPA to promote the use of databases such as IRIS and the WMPT for making risk management decisions and setting waste minimization priorities, however, when those databases contain outdated information that has not been subject to external peer review, particularly when more up-to-date information has been provided to the Agency. EPA's consistent failure to utilize up-to-date information undermines regulatory programs that rely on Agency databases, and results in inappropriate risk management decisions and misdirection of resources towards reducing the usage of chemicals which in fact do not pose hazards to human health and the environment. (D25:15)

- EPA recently implemented a pilot program to improve the process of including information in the IRIS database. The Panel hopes that this effort will facilitate more timely revisions to the IRIS database and greater public input to the process. However, as yet this has not occurred. (D25:15)

- At a minimum, the Agency should commit to reviewing and expeditiously updating the information on these chemicals in the WMPT when the reports become available. (D25:13)

- To the limited degree that it is transparent from the User's Guide appendices, the reliability of the data used is questionable. The User's Guide notes that, for most of the high quality data, the calculations were made using only "data collected through August 1994." (p. C-5) In addition to excluding the most recent data, the Agency has failed to design a mechanism to ensure that new data and methods are reflected in WMPT and the Priority List. If the Agency moves forward with finalizing WMPT, AIHC strongly encourages the Agency to assess lessons learned from programs that prematurely took on national significance—such as the Integrated Risk Information System (IRIS) database—and ensure that the data used (1) are the most reliable, up-to date data available and (2) are kept evergreen through an established Agency review mechanism. (D30:10)

- Prior to using WMPT chemical scores to help select "PBT" chemicals, missing data should be identified and incorporated for the 42 chemicals that score highly (8 or 9) on either the human health risk potential or ecological risk potential categories but cannot be given an overall PBT score due to missing data. (E1:11)
- The WMPT lacks the ability to input additional data that would address the deficiencies associated with the current criteria used in the scoring for persistence and bioaccumulation. (D35:7)

- A process needs to be created in which data input into the model is subject to a peer review process. (D37:ii)

- The WMPT does not appear to allow for the updating of individual data. (D38:1)

- No mechanisms is provided for periodic update of the WMPT and the PCL to ensure use of new information and incorporation of improved understanding of chemical toxicity, persistence, and bioaccumulation. (D41:1)

- EPA clearly states in the Notice that: "The scoring algorithm is a screening tool and is not intended to be used as a substitute for detailed risk analysis (62 Fed Reg 33869)." Unfortunately, the free publication of this admittedly simplistic Software can only encourage its use as a substitute for correct and detailed risk analysis. To the extent that the Software attempts to prioritize chemicals based on risk, it has been published prematurely without sufficient analysis of the results for any given compound compared to actual risk. (D12:4)

- Establish a formal process by which interested stakeholders can petition for revisions to WMPT-derived scoring based on new and /or more accurate information. Such a process would ensure that (1) all available data are reviewed; (2) the data used to support WMPT chemical scoring are the most recent and reliable; and (3) actual data take precedence over extrapolations from actual data or model predictions. (D49:cover, 29)

- If the WMPT is to be available for use, it should have a procedure for updating and reviewing the data, rankings, and data quality considerations on an annual basis, at least. There should also be a procedure for submittal of data from outside sources with a formal EPA review and response within a reasonable time frame. (D32:7)

- As EPA has stated, the data set used for developing WMPT is one in constant flux, and should be updated as the science behind the tool improves. The Agency should establish the procedures for updating the WMPT at regular intervals to ensure that the tool remains current. These procedures should be put in writing to facilitate collection and evaluation of new scientific data. (D29: cover1, 2,3)

- To be an effective, accurate, and useful tool for all stakeholders, WMPT must also include an automatic procedure for updating chemical rankings as EPA rulemakings and regulatory determinations deregulate or downgrade the risks of listed chemicals. (D54:3)

- The WMPT does not include a process for updating and correcting PBT data for individual chemicals as new data becomes available. Such a process is necessary if the WMPT is to be effective. (D27:i, 15)

- There is a concern that once a hazard ranking is published for a phthalate ester, it will be very difficult to obtain revisions, even where EPA staff acknowledge that the ranking is based on flawed data. This has been the case for EPA's 1986 Quality Criteria for Water for Di(2-ethylhexyl)phthalate (DEHP), which EPA has admitted is incorrect but has yet to revise. EPA needs to develop methods for ensuring the accuracy of values in the WMPT and updating those values as new information is developed. (D18:19, 35)

- The WMPT is too large to be easily or quickly amended. (D18:19-20)

- To improve the underlying data in WMPT, stakeholders should have the opportunity to supply measured data in cases where they disagree with the results of the tool. EPA should not put out a prioritized list unless the

stakeholders have the opportunity to challenge it. The public comment period for the draft list does not allow sufficient time for stakeholders to react, since the data used in the tool are not transparent. The stakeholders need a lot more time to figure out what data have been used in order to be in a position to challenge it. (S1i:12)

- It is important to keep the tool updated, possibly annually. IRIS and HEAST databases are updated triennially. Many of the EPA databases used in the tool are not currently updated frequently enough. OPPT has processes to review data and might be the place to send updated data. In the case of WMPT, the data would probably first be sent to OSW, who would then coordinate with other offices within EPA to have the data considered and reviewed. EPA should set up a formal loop within the agency to handle data provided from stakeholders. (S1i:12,13)

- EPA should enhance WMPT by including more layers of analysis that are generally applicable, such as partitioning data. However, modifications should not increase the level of specificity of the tool. The tool should be close to a risk assessment tool, but should not become analogous to a risk assessment tool. (S1e:21)

- As stated by Silicones Environmental Health and Safety Council, EPA should rectify the flaws in the draft WMPT as well as create a formal process for application of WMPT which mandates that (1) reliable and accurate data available to the public must be used, and (2) revisions to WMPT scoring based on new or more accurate data can occur upon petition by an interested stakeholder. (D52:1)

- EPA must be committed to updating and refining the tool if it is going to have long-term value and validity. (D55:cover2, 2)

- As the science continues to evolve and the various databases grow, EPA should make every effort to consistently review and update the prioritization tool in the future. (D57:2)

c. Other

- The scores of all chemicals on the WMPT should be reviewed carefully and promptly revised. As new data become available, a mechanism must be in place for additional corrections. In the meantime, all WMPT users should immediately be informed of the possibility that inaccuracies are contained in the database. (D45:3)

- In scoring toluene diisocyanate (TDI) and methylenediphenyl isocyanate (MDI), EPA used outdated computer programs without considering updated and corrected versions; ignored well-documented physical and chemical properties in evaluating exposure (bioaccumulation and persistence) potential; omitted good quality animal and human data in evaluating human health effects; and relied on models, reports and assessments that had not been subject to peer review or submitted for appropriate public notice and comment. (D19:14)

- EPA should improve the transparency of the WMPT by fully disclosing to the public all databases, sources, scoring methodologies, and calculations used in the WMPT for each chemical. (D27:76)

- A mechanism for periodic update of WMPT and the PCL should be included. (D40:9)

- EPA should provide the public with adequate time to review proposed values on the phthalate esters. The current review period (111 days) is inadequate due to the complexity and non-transparency of the sources and methods employed in calculating the current values. Since the WMPT is not required by statute or judicial decree, there is no imperative to limit the comment period. (D18:i, 2, 11)

- In recognition of the success of current methodologies, EPA should make extensive use of predicted methodologies to include data for chemicals to allow for their scoring/ranking. (S1e:20)

- Consider a broad range of available data. If you use only data which has been used for regulatory purposes, it will never be high quality. Data which has been peer reviewed in any country would be the highest quality. Data written in a journal might be considered medium quality. It is also important for users to be aware of the quality of the data that was being used in the model. This might spur new research on the effects of chemicals with little, or lower quality data. Indicate data quality for each number so that P, B, and T would each be associated with a data quality of high or low. This would provide information on the data quality of the chemicals in the priority list. (S1s:38)

12. Speciation, Isomers, and Chemical Groups

- Trace metal speciation (i.e., Total and Dissolved concentrations) as well as synergy of multiple chemicals is becoming more relevant for assessing environmental health. Could they be eventually incorporated into the WMPT? (P1:39)

- There is inconsistency in ranking of different species of trace metals that needs to be remedied. For example, the Cadmium atom is the mode of aquatic toxicity and bioaccumulation for all the Cadmium species listed in the PBT database. In a log scale, there is likely little difference in toxicity between Cadmium alone, and CdCl, CdCN, CdBr, CdAcetate. Therefore, the PBT score for one species say Cadmium with high quality data could be applied to the other species that have lower quality data. The result would be a more complete PBT ranking for the Cadmium species with less data. (P1:40)

- EPA's practice of using a chemical class-based approach to assign toxicity values is inappropriate for individually ranking chemicals. This practice does not account for differences among chemicals which may vary widely within a class (D27:49-50).

- The WMPT and Prioritized Chemical List should recognize the special considerations that apply when a metal such as nickel is present in an alloy. In this regard, it is important to understand that alloys are not simply mixtures of the parent metals. The physical and chemical properties of an alloy reflect not only, their elemental composition but also the history of heat treatment (and cooling) through which the alloy was formed and any mechanical working to which the alloy has been subjected. Because an alloy has different physical and chemical properties from its parent elements, it exhibits different properties than the individual elements from which it was formed. Since metals and alloys are not soluble in water, their bioavailability depends in part on an oxidizing chemical reaction referred to as corrosion that produces a different metallic species. But the potentially "toxic" metal in an alloy (e.g., nickel in stainless steel) may very well be added in order to increase resistance to corrosion, thereby reducing the extent to which potentially toxic metal species can enter the environment from the alloy and become potentially bioavailable. In part as a result of this difference in bioavailability, the alloy itself will have different toxic properties from its parent elements. The WMPT should at least recognize this point, so that users of the tool will not assume that alloys should necessarily be ranked the same way as their parent elements. (D56:3-4)

- Metal releases from manufacturing facilities are predominantly in the form of metal compounds, not elemental metals. Therefore, the potential for living organisms to encounter elemental metals from these emissions is very small. (D43:5)

- EPA has failed to consider differences among metal species in calculating ecological toxicity scores. The potential risk to human health and the environment presented by metals varies markedly among the metal salts and species (e.g., the bioavailability of selenium varies depending on valence state; hexavalent chromium is of far greater concern than the trivalent form). Despite the marked differences, the WMPT does not assess the ecological toxicity of each metal species separately. Rather, the WMPT bases the score for elemental metals on data from the highest scoring salt or species of the metal. EPA's failure to distinguish between metal species represents a significant deficiency in the WMPT. For example, the largest percentage of chromium present in industrial wastes is in the less toxic, trivalent form of the metal, resulting in an excessively conservative ranking for chromium. Because it does not accurately distinguish between toxic and non-toxic metal species, the scoring method for ecological effects also has little relevance to the goals of waste minimization programs. (D43:i,16-18)

- We believe the WMPT methodology is unduly arbitrary and significantly flawed, particularly as it applies to metals. We do not understand, for example: why speciation is largely ignored in assigning scores to metals. (D56:3)

- In the WMPT, nickel has been assigned a score of 3 for human toxicity. It is not clear whether this is intended to refer solely to elemental nickel, the substance whose CAS number is identified on the PCL, or to elemental nickel and all nickel compounds. If the listing of nickel in the WMPT is intended to encompass all nickel species, it is scientifically unsound and unsupportable because it ignores the importance of speciation in evaluating the potential toxicity of metals. Empirical evidence of the importance of speciation for metal toxicity is well recognized. National Toxicity Program studies found differing toxicity results for different nickel species (i.e., nickel subsulfide, nickel oxide, nickel sulfate hexahydrate). EPA itself has recognized the significance of speciation in the case of nickel, by distinguishing among different nickel species for purposes of cancer classification under the Clean Air Act hazardous air pollutant program. The most recent Threshold Limit Value recommendation of the American Conference of Governmental Industrial Hygienists (ACGIH) proposes three different carcinogen classifications for different nickel species: Insoluble nickel compounds and nickel subsulfide are placed in category Al Confirmed Human Carcinogens; Soluble nickel compounds are placed in category A4 -Not Classifiable as a Human Carcinogen; and Elemental/metallic nickel is placed in category A5 -Not Suspected as a Human Carcinogen. The critical importance of metal speciation should be reflected in the WMPT. (D56:9-11)

- EPA has not identified elemental nickel as a human carcinogen, and the evidence clearly would not support such a classification. The only forms of nickel identified in the IRIS database as known or probable human carcinogens are nickel subsulfide and nickel refinery dust from pyrometallurgical sulfide nickel matte refining (both of which are classified by EPA as Group A Human Carcinogens) and nickel carbonyl (which is classified by EPA as a Group B2 Probable Human Carcinogen). The ACGIH recently classified elemental nickel in category A5 signifying that it is "Not Suspected as a Human Carcinogen." [See supra p. 11]. Furthermore, the International Agency for Research on Cancer ("IARC") has classified metallic nickel in category 2B, which equates to EPA's WOE category C. [See User's Guide App. C at C 11]. In these circumstances, we question whether elemental nickel should be assigned a Human Toxicity score on the basis of cancer effects at all. But, even if it is assigned a cancer-based score, the score clearly should not be 3. Whether it is evaluated on the basis of noncancer effects or, more questionably, on the basis of cancer effects, elemental nickel should not be assigned a Human Toxicity score higher than 2. Furthermore, this would be true even if EPA intends to ignore speciation entirely and apply the WMPT ranking to elemental nickel and all inorganic nickel compounds. (D56:9-14)

- As noted by EPA (1997b, p. 16), "Risk is a function of toxicity and exposure." Bioavailability and hence toxicity (or lack of thereof) of metals such as zinc are related to metal speciation (the distribution of the forms or "species" in which a metal can occur), which is dependent upon a number of chemical, biological, and physical factors which are constantly in flux in natural settings (Allen, 1993; Xue et al., 1995; Peijnenburg et al., 1997; Chapman et al., in preparation). Persistence is not of concern unless a substance is or can become bioavailable. In the case of substances (metals / elements) such as zinc, this means that the free ion or particular inorganic complexes must be present or potentially present at toxic levels before such substances are considered hazardous (Allen and Hansen, 1996). Thus only by determining bioavailability can exposure and toxicity (and hence risk) be determined. (D50:3b)

- It is difficult to assign metals a relative score due to the influence of their valence state, degree of oxidation, or organic transformation on their bioavailability. It would make more sense to list metals as a separate category or to provide chemical-form specific information (e.g., chromium III vs. Chromium VI). (D31:14)

- Metals are not addressed appropriately by the WMPT methodology. Metals appear in different forms in the environment, and each form has different toxicity, bioaccumulation, and persistence characteristics. The system assigns the worst case data for any metal form, rather than assigning the values to each form of the metal. We recommend that P, B, and T scores be assigned to each form of the metal individually so each form of the metal ends up with a complete score. (D32:cover2)

- PBT metals data should be specific to individual metal compounds. Several metals are referred to by CAS numbers as the bulk metal, yet P, B, or T data are presented for other compounds of the metal. Data should be used that are specific to the CAS number that is cited. Given the markedly different chemistry of metals depending on the speciation in the environment (e.g., silver versus silver nitrate), the assessment should be done individually for each metal species. (D32:6)

- It is difficult to assign metals a relative score due to the influence of their valence state, degree of oxidation, or organic transformation on their bioavailability. It would make more sense to list metals as a separate category or to provide chemical-form specific information (e.g., chromium III vs. Chromium VI). In addition, there is no distinction between different forms of hexane, nor their different toxicities. EPA should follow a simple rule of thumb: if different chemical forms of a chemical have separate toxicities, then separate entries should be made. (D29:7)

- Several Association of State and Territorial Solid Waste Management Officials (ASTSWMO) meeting participants noted that specific metal compounds are not part of the 900 or so chemicals scored by WMPT so far. (T2:2)

- EPA should score elemental metals for ecological effects based on representative or average data rather than the most toxic metal salt or species. (D27:80)

- The application of WMPT to metals provides an example of some of the flaws in the scoring system. For example, several metals are referred to by CAS number as the elemental metal, yet persistence, bioaccumulation, or toxicity data are presented for other compounds of the metal. Data should be used that is specific to the referenced CAS number. In some cases (e.g., silver) this error reflects the flaw in the database underlying WMPT. Silver is given an ecological PBT score of 3/1/3, based on metal persistence, lack of bioaccumulation, and "toxicity" values for silver derived from silver nitrate. Although silver nitrate is toxic to aquatic life, silver metal, which is identified by CAS number in the WMPT, is not toxic. Therefore, a PBT rating of 3/1/1/ would reflect the data for silver metal more accurately. If silver nitrate were assessed, the very short half-life of this species in water would suggest a PBT rating of 1/1/3. To cite another example, vanadium is assessed as 3/3/3. The species vanadium that were assessed as toxic and bioaccumulative are not presented; therefore this assessment cannot be evaluated for accuracy. Given the markedly different chemistry of metals depending on the speciation in the environment, assessing all species of metal under the generic name of the element may lead to decisions that protect against or minimize "hazards" that have been improperly identified. (D30:8)

- WMPT does not consider the toxicity of sub-species of chemicals, some of which are much less toxic than others. For example, copper appears in various forms. The ionic form of copper is toxic at very low concentrations, whereas complexed copper is basically nontoxic. EPA's standard approach to regulating chemicals has been to assume that chemicals are present in their most toxic form. This is not accurate and has unfairly led to regulatory burdens being imposed on facilities that use and/or release, discharge, or transfer such chemicals off-site. An article published in the June 1997 issue of *Water Environment and Technology,* entitled "Water Quality Criteria for Copper" (Appendix 1), states "Laboratory-derived numerical water quality criteria for copper, developed by EPA in 1984 and updated in 1993, assume that the toxic form of dissolved copper exists in biologically treated effluents when, in fact, it does not. This causes erroneous permits to be issued, municipal resources to be misdirected, and industrial facilities to be adversely affected." If EPA wants to provide relative rankings for chemicals, it must distinguish between toxic and non-toxic forms of listed chemicals. (D54:3)

- By failing to assess the various species of each substance, especially metals, the WMPT inappropriately scores toxicity. For example, no distinction is made between trivalent chromium, an essential human micronutrient, and hexavalent chromium, which has been linked to certain health impacts. The result is that more benign species of

certain substances will be subject to overregulation while more hazardous species will be potentially under regulated. (D9:5; D10:4)

- The WMPT algorithm fails to differentiate between the different human health hazard potentials associated with different metals. First, there is inadequate differentiation of human toxicity potential of different metals. Second, by using ecological P and B as surrogates for human exposure and rating all metals high on P, WMPT assumes that all humans have the same exposure potential for all metals. (D32:5,6)

- Potential exposure is determined by assessing a substance's bioavailability. For metals, bioavailability varies significantly among the different species of a metal and also is impacted by environmental media. Accurate risk prioritization requires consideration of both bioavailability and metal speciation. (D9:4; D10:4)

- To improve the technical basis of bioaccumulation scores, reliable measured BAF/BCF data should always be used in preference to model predictions. Information on specific isomers within a broad class should be used when appropriate for determining bioaccumulation scores. This approach recognizes that homologous chemicals with common structures will be metabolized similarly. (D29A:14)

- Some chemicals are grouped without distinguishing their different toxicities. For example, n-hexane and iso-hexane are grouped as "hexane." N-hexane is more toxic than iso-hexane, and therefore, would be assigned a higher toxicity score if these materials were addressed separately. (D31:14)

13. Other

a. General

- I like the format, especially the scoring and customizable report structure. One item for inclusion would be customizable weighting factors (for scoring chemicals) similar to the Analytic Hierarchy Process. In that way, a user group would be able to increase the weight of a given parameter (e.g., human impacts). (P1: A-3)

- Note that acute toxicity and chronic toxicity are important and that both should be considered for inclusion in the model. Both are used in the risk assessment process, when appropriate. (S1:40)

- EPA should reevaluate the level of technical inputs and complexity in the model to ensure that it does not creep into a full scale evaluation when it really wants a "screening tool." (S1:40)

- EPA has already developed an index of the environmental hazard posed by various chemicals. Under CERCLA, EPA establishes RQs, or quantities of chemicals that, if released to the environment, require notification to the National Response Center. These data exist for substances designated as hazardous under just about any existing environmental law. The numbers have been developed only after considerable research, peer review, and public comment. The inverse of the RQ (1/RQ) is perhaps the best overall measure of the environmental hazard of a chemical available. In measuring persistence, the standard used in the scientific community is the half-life. In measuring bioaccumulation, the standard measure is a partitioning coefficient (commonly water: n-octanol). However, both of these issues have already been considered by technical experts and have been subject to public comment in establishing CERCLA RQs. As such, they need not be introduced in the proposed model if the RQ is used as the measure of potential environmental hazard. In essence, the model can be simply expressed as: RISK = Quantity/RQ. With this equation, you are now able to expand the model to all CERCLA hazardous substances (over three times as many chemicals as currently included) and newly regulated chemicals can be added with no need to re-invent work already being done by the CERCLA regulatory development staff. (D70:2)

- EPA stated in the National Plan that the WMPT model "will be based primarily on the inherent hazards of constituents, but also will be applicable to hazards posed by management practices." EPA emphasized that both the screening tool and list of high-priority constituents will be "based on risk." The draft WMPT and PCL that EPA has released, however, are neither flexible, applicable to hazards posed by management practices at the facility level, or based on risk. These failings seriously undercut the value of the WMPT and PCL to assist stakeholders in meeting the waste reduction goals of the National Plan. (D48:4)

- In general staff that reviewed the WMPT are supportive of EPA's work to develop a Waste Minimization Prioritization Screening Tool that focuses on Persistent Bioaccumulative Toxics. We are glad to see the tool and believe it will have promise in helping to identify waste minimization priorities and could be a valuable screening tool in other applications. Specifically, one of the aspects of the tool we liked are having many chemicals and environmental persistence, bioaccumulation, BCF and other toxicological data in one place. (D77:1)

- The WMPT should be refined to include synergistic effects of toxics if possible. (D77:2)

- Using use clusters seems like a large improvement over earlier attempts at hazard ranking in air programs. At least this ensures chemicals with similar end users are compared. (D77:attachment)

- It appears that EPA has not followed, in full, the recommendations made by the SAB in reusing its Use Clusters Model prior to or during the modifications made to the model to derive the WMPT. In addition, it is unclear whether or not this application of the Use Clusters Model is appropriate for use by industry in identifying waste

streams for reduction. Therefore, Eastman recommends that immediate SAB review be sought for the WMPT, before EPA distributes and recommends the use of the tool by any and all parties. (D75:12-13)

- EPA is to be commended for its efforts to provide industry with a means of prioritizing wastes for minimization efforts. However, the model, as proposed, does not reflect scientific realities at all. (D70:1)

- Oregon Department of Environmental Quality recommends that EPA: (1) Build in additional subfactors and add additional data to the WMPT, when available, to enhance the ecological exposure potential factor. Specifically, include, (a) air quality and deposition data, (b) chemical partitioning data (i.e., from air to water), (c) chemical mobility data (i.e., chemical movement from soil to groundwater or surface water to groundwater),(d) fate and transport data; (2) Examine ways to include information on synergistic effects in the persistence, bioaccumulation and toxicity subfactors; (3) Maintain the use of estimated data from empirical models when reliable, repeatable, experimental data is not available. Do not rely on case studies that represent regional or specific situations. (D65:2)

- Oregon Department of Environmental Quality recommends that the EPA expand the chemical information in the WMPT database, or ability of model, to include chemicals that are new on the market, particularly those targeted by EPA as less toxic chemicals. (D65:2)

- EPA should take a more thoughtful approach in its weighing of toxic parameters. While the effort to create a simple and flexible tool is the obvious driver to the omissions in the WMPT, BHP Copper believes that the software technology exists to fold a range of additional parameters into a tool for waste generators which produces a more dynamic result with practical meaning to its users. (D61:2)

- BHP Copper believes that a more rigorous scientific approach can be applied to the serious issue of waste minimization in a way that accurately reflects the substances in question and the other, often critical, parameters which combine to determine the substance's risk potential. For this reason, BHP Copper hopes these comments provide assistance to EPA in crafting a useful prioritization list. (D61:3)

- The data and methodologies used in WMPT for ranking chemicals for waste minimization must be scientifically valid. (D69:7)

- The ranking of chemicals by WMPT must accurately reflect risks that may potentially exist during the life cycle of the chemical as a waste. (D69:7)

- Validation of the WMPT model should be completed before the WMPT is finalized and applied to identify and rectify deficiencies. (D49:2)

- There needs to be specific notation that many of the chemicals are not persistent, bioaccumulative, or toxic and that a score of 6 is a "no concern" level. (D33:2)

- There are serious concerns with respect to instant assessments of risk-based on simplistic categories which the "Prioritization tool" algorithm portion of the Software attempts unsuccessfully to undertake. (D12:3)

- The ranking scheme used in the WMPT is deficient because it does not acknowledge that some chemicals are not persistent, toxic, or bioaccumulative; such chemicals should receive a score of 0 instead of 6. The current scheme is misleading and gives the impression that all chemicals on the PCL are of concern. (D27:58-59, 77)

- There are many chemicals used throughout the modern economy which are valued specifically because of their benign persistence. By persisting in the environment under adverse conditions, many chemicals, and especially

color pigments, perform valuable functions. If these compounds were to break down quickly in the environment, the functions performed by those chemicals would require continuous replacement. Such continuous replacement would require high quantities of time, energy, production and pollutants. A common example of this would be the bright red traffic stop sign. Without safe, non-toxic compounds which persist in the environment, the stop sign either has to be continuously repainted or replaced. Such results are not efficient and certainly do not protect human health or the environment. Indeed, the results are simply wasteful. Similar results and examples would include vehicle coating, outdoor signs, printed materials, products made from plastic resin, and building materials. Under the current algorithm, color pigments would engender a score of a at least 10. Such results are completely out of proportion with the risk posed by color pigments. Organic color pigments are extremely stable in the environment, they are not shown to be acutely or chronically toxic and they have not caused or created toxic conditions in the environment. (D12:9)

- The simple parameters used by EPA (toxicity, persistence, and bioaccumulation) fail to provide meaningful assessments of risk potentials for comparison between chemicals. (D9:4; D10:3)

- The WMPT does not adequately discriminate among chemicals on the basis of PBT characteristics. (D27:ii)

- Waste minimization priority setting should be based on risk, with a focus on persistence, toxicity, and bioaccumulation potential (as the Waste Minimization National Plan and the WMPT are based). (D27:8-9)

- The WMPT does not follow the principles essential to a sound policy for addressing PBTs. (D27:11-12, 19)

- EPA's approach is an inappropriate use of PBT screening values; these values should be used as benchmarks only. The limitations of the data prevent EPA from using PBT data for this sort of precision. (D27:i-ii, 16)

- The contribution of hazardous wastes to the overall emission inventory of a particular chemical is not considered. (D27:18)

- When scoring both human and ecological toxicity, comparable endpoints must be used. Use of a single endpoint would enable EPA to focus appropriately on data collection/update for measured data. (D27:80)

- The WMPT does not incorporate critical Science Advisory Board comments on the Use Cluster Scoring System. (D27:ii)

- Placing a high level of effort on pesticide materials that are already being minimized in waste does not produce additional benefits and EPA should focus on non-final product materials. (D36:5-6; D39:2)

- The EPA Science Advisory Board's review of the OPPT "Use Cluster Methodology" should not be sufficient to address the revised methodology that EPA has applied for different purposes in the WMPT and Priority List. (D30:2)

- The release of this scoring software without sufficient review creates the practical impact of a rulemaking effort which will impact the industry for many years, without the procedural safeguards that the rulemaking provides. Since the impacted public has not had a reasonable opportunity to provide comment on the goals of the program, the scoring algorithm or the priorities created by the algorithm, the initiative has become an inappropriate rulemaking effort. (D12:7)

- The release of the software, which is fully functional, is not analogous to a notice of proposed rulemaking used by EPA in normal rulemaking efforts. The premature release of the operational software inappropriately sets

priorities and unnecessarily pressures manufacturers to react to the result of the algorithm without either sufficient analysis or reasonable quantified risk analysis. (D12:8)

- EPA should release the algorithm and prioritizing analysis in the form of a notice which the public can comment on in a rulemaking. These comments should include the priorities set by the design, the related accuracy of the score in estimating risk, the absence or inclusion of the exposure potential, the need for the software and the actual functions the software will be used for. This entire process should have proceeded the release of the software in a functional format which can be misused by the public. (D12:8)

- As reported in the 1995 Toxics Release Inventory (TRI), environmental releases of methyl chloride in the United States are insignificant. Industrial emissions of methyl chloride are estimated to account for considerably less than 1% of the total found in the environment and should not be considered for waste minimization. The ATSDR recognizes that "most releases of chloromethane will be to air, since it is a gas at ambient temperatures and manufacturing practices suggest that little will be discharged by any other route." The TRI data show that of the 4.19 million pounds of methyl chloride released to the environment in 1995, 4.08 million pounds were released to air. This figure is insignificant compared to natural sources. In addition, only 57,255 pounds of methyl chloride were released to water, and an almost nonexistent 35 pounds were released to land. From a waste minimization perspective these releases also are insignificant. Moreover, the WMPT models focus on releases in water. To the limited extent that methyl chloride is released to water, it will evaporate rapidly. In the aquatic environment there will be minimal, if any, opportunity to reduce or prevent methyl chloride. Thus, methyl chloride should not be identified as a priority for waste minimization. (D53:3-4)

- Listing methyl chloride on the WMPT and PCL will create impressions that there is a high level of concern about potential health hazards, that there is an ability to achieve reductions in emissions and that achieving reductions in emissions will have a material impact on human exposure and risk. None of these impressions is correct. The limited industrial releases indicate that methyl chloride does not pose risks that can be minimized. Attempts to reduce or prevent methyl chloride emissions will be meaningless. "Chloromethane is a ubiquitous constituent of air and probably drinking water. As such, the general population will be exposed to background levels at all times." Inclusion of methyl chloride on the WMPT and PCL will lead to misunderstandings concerning the utility of waste minimization efforts aimed at methyl chloride and skew the proper prioritization of other chemicals. Given the insignificant environmental releases of methyl chloride and the minimal contribution from industrial sources to overall emissions, methyl chloride is not a priority for waste minimization. EPA should remove methyl chloride from listing under these prioritization tools so that methyl chloride is not stigmatized by the mere inclusion on the WMPT and PCL and so waste minimization efforts can be properly focused on chemicals for which real reductions can be achieved. (D53:5)

- Tris(2,3dibromopropyl) phosphate is no longer produced commercially and therefore can be removed from the WMPT and PCL. (D21:i, 15)

- SAB's Environmental Engineering Committee reviewed the UCSS chemical ranking methodology from which the WMPT was developed and suggested numerous improvements to the methodology, including the means to account for the performance of substitute chemicals and the incorporation of a cost-benefit filter. EPA's Waste Minimization Team's response to these comments was that the [WMPT] developers were including the suggested revision. However, these suggested changes have not been incorporated. (D31:7,8)

- The term "fenceline" can be misleading, particularly as it is often used to describe exposures at or near a geographic or facility boundary. Perhaps a more "toxicologically appropriate" term could be chosen (e.g., cut-off, bound, limit).

- The WMPT does not incorporate many of the comments on the UCSS, the scoring algorithm on which the WMPT was based, suggested by the Science Advisory Board (SAB). Many of the criticisms of this board were not addressed by EPA. For example: the WMPT omits many important data sources; the WMPT utilizes several databases (especially those including ecological data); the WMPT counts persistence and bioaccumulation components are both counted twice (first for human health risks and then for ecological risks); the WMPT uses estimated rather than actual data; the WMPT has no mechanism for tool validation through industry reviews; the binning/fenceline approach involving three categories to ranking chemicals is unsophisticated and blunt; the WMPT uses noncomparable data sources; and there is no rationale for establishing the fencelines for the various factors. EPA should incorporate all SAB recommendations for improvements in the UCSS and all applicable recommendations to the WMPT. (D27:61-68, 76)

- The SAB should review the WMPT before it is released to the public in order to review the applicability of the SAB's criticisms of the UCSS as well as consider new, unique issues raised by the WMPT (such as differences in the databases used for the WMPT and the UCSS, and the scientific integrity of the WMPT's approach to weighting bioaccumulation and persistence). (D27:68, 76)

- EPA should consider synergistic effects between the chemicals in scoring the chemicals for the PCL. (T1:3)

- A suggested criterion for selecting priority PBT chemicals is looking at how difficult or easy it would be to track a particular chemical (e.g., by using purchasing data). (T1:3)

- OSW should examine whether hazardous waste or total releases should be addressed by WMPT. OSW may be boxing themselves in by focusing on hazardous wastes solely. This is a relevant issue because it determines whether the selection criteria should focus on exposure through use or not. (T1:3)

- A possible criterion for selecting priority PBT chemicals could be the total number of PBT chemicals in the waste stream (i.e., co-presence of a PBT in a waste stream with other PBT chemicals). (T1:4)

- Allow the user to change weighting based on state/local conditions or ask what if? (T5:3)

- Why have all of the data for 4,000 chemicals when at present only 800 are ranked by PBT risk? (T5:3)

- The more complex the system, the harder it is to defend in front of an administrative law judge or the public. (S1:5)

- The focus of WMPT is more on chronic rather than acute risks. Acute risks are important, especially if a substance is near a drinking water source, and should be considered further in the development of the next version of WMPT. (S1:6)

- One participant suggested that the (physical) matrix in which the chemical of interest is located be addressed in the WMPT algorithm. This is particularly important for chemicals under pressure in a tank. (S1s:31)

- A "border analysis" should be conducted to ensure that the screen does not miss other chemicals of concern. (E1:7)

- WMPT focuses solely on the surface water pathway, however, other pathways (e.g., air transport) may also be a concern from the standpoint of exposure and risk. One short-term approach to address this issue is to consider multi-media concerns (e.g., potential for long-range transport, persistence in various media, transfer between media) in developing the criteria that will be used subsequently to narrow or augment the list of candidate PBT chemicals from the WMPT (i.e., for the National Measurement List). (E1:9)

- GE Silicones, General Electric Company (GES) supports EPA's initiative to develop a tool for screening of potential PBT risk chemicals. GES understands EPA's desire for simplicity in designing the tool, but simplicity cannot mean the tool produces inaccurate results, because, this will, in turn, lead to inappropriate waste minimization priority setting. (D52:1)

- Information on synergistic effects of chemicals should be included, if possible. (D55:5)

- The model should look at ways to include information on chemicals new to the market, so recommended chemical substitutions can be evaluated using WMPT. (D55:5)

- EPA should avoid risk creep where a simple screening tool is replaced by a complex, multi-media, toxicology, fate and transport algorithm. EPA should review the software and documentation and perhaps reduce the complexity of the tool to make it a truly usable and appropriately named screening tool. (D55:5)

b. Customer Surveys

- Of the participants at the Midwest Pollution Prevention Conference that filled out customer feedback surveys, four found the scoring of chemicals, waste streams, facilities, and industrial sectors based on PBT and quantity "very useful," while three found it "useful." (T3:2)

- Seven of the respondents who completed customer feedback surveys at the National Pollution Prevention Roundtable believed that scoring of chemicals, waste streams, facilities and industrial sectors based on PBT and quantity would be "very useful." (T5:2)

- Of the participants at the Midwest Pollution Prevention Conference who completed customer feedback surveys, three thought the potential for WMPT to provide information on media-specific concerns would be "very useful," while four thought it would be "useful." (T3:3)

- One respondent who completed a customer feedback survey at the National Pollution Prevention Roundtable indicated that media specific concerns were "not useful." This individual is affiliated with an Academic setting and noted that he was unfamiliar with the term PBT. (T5:2)

B. Draft Prioritized Chemical List

- EPA should modify the PCL ranking for "antimony" to refer only to antimony potassium tartrate. Alternatively, the listing could be changed to "antimony—water soluble forms" with an explanatory note that antimony trioxide and other oxides are excluded from the category. (D78:6)

- As we understand it, chemicals were placed on the PCL purely for the reason that complete data sets were available on those chemicals and that, indeed, a score of 10, 11, or 12 constitutes a relatively benign score. While sophisticated analysts may well understand this situation, to most people, it appears that a chemical being placed on this list in some ways constitutes indictment by EPA of the material. We understand that this indictment is not the intent of the software, but the reality of the indictment remains and must be dealt with. Therefore, we strongly suggest that EPA finalize the software but not publish a complete list of any and every material on which data exist. At a minimum, the software should be published as an analytical tool, and if necessary, those materials which EPA judges to be seriously hazardous should be provided to the general public. (D80:2)

- There was a consensus by the consortium that county-wide, prioritized chemical lists have to be medium-specific. That is to say, there should not be a single prioritized chemical list for a community. Rather, a county-wide list should be specific to water, air, and soil, because exposure routes are different for chemicals in air, water, and soil. In addition, medium-specific lists will help indicate where pollution prevention actions need to be concentrated. (P1:9, 10, 37, 38, 45)

- Often half of the chemicals of concern to facility participants did not have PBT scores. There are, however, chemicals with very similar structures that have PBT scores. For instance, sulfuric acid has no PBT score, but is similar in structure to sulfuric acid ester, which has a PBT score. Using the PBT score for sulfuric acid ester as an interim proxy for sulfuric acid would provide the user with some information about its relative risk. Qualifiers on what data is incomplete would need to be explicitly stated for the viewer. (P1:40)

- One participant suggested that the range of overall chemical scores be changed from 6-18 to 0-12 to more clearly identify chemicals of no PBT concern. (T6:1)

- Lower scores for the bioaccumulation and persistence factors for pentachlorophenol are appropriate. The bioaccumulation score for pentachlorophenol should be reduced from 3 to 1 based on the pH dependent log K_{ow} of 3.32, or from 3 to 2 based on corrected BAF of 600-650 or the reported BCF value of 772. Using more recent data on biodegradation and consideration of photolysis, the persistence score similarly, for penta should be reduced from 3 to 2. This would lower the overall score for pentachlorophenol to 11 (but no more than 13) from its current value of 17. (D48:23)

- Pentachlorophenol's relatively high negative PCL score distorts the chemical's environmental record. Scientific studies have shown that: wood preservatives such as pentachlorophenol do not aggressively leach into the ground or waterways, drinking water supplies, or adversely effect marine life; and proper handling and use of preserved wood poses no increased risk of cancer or other illnesses among humans, animal, and marine life. The problems associated with the use of chemical and non-chemical alternatives to pentachlorophenol, on the other hand, cannot be ignored. These problems include increased energy consumption and the risks associated with substituting steel, concrete and other building materials for wood. (D48:10)

- The WMPT does not acknowledge that some chemicals on the list are not persistent, toxic, or bioaccumulative. Yet these chemicals will receive a score of 1 on each of the factors, resulting in the minimum overall score of 6. (D75:17)

- EPA's WMPT is too unsophisticated, is flawed, and Eastman cannot agree that all chemicals have been ranked by their PBT characteristics appropriately. Indeed, a large number of chemicals are not ranked at all, because of the lack of PBT data. Unranked chemicals may be of greater concern than many of the ranked chemicals. (D75:10-11)

- Recent estimates show there are approximately 80,000 different chemicals on the TSCA Inventory today. In light of this fact, it is unclear why the 879 chemicals on the Draft PCL were selected to appear on the list. Moreover, it is unclear why the 4,727 chemicals in the WMPT were selected to appear in the tool. EPA should make its chemical selection criteria known to the public. (D76:5)

- A "reality check" of the Draft PCL demonstrates its misdirected focus. Reilly believes that use of the Draft PCL would result in misdirected focus to reduce waste streams that do not have the same potential for harm as lower scoring streams. (D76:6)

- Some chemicals receiving an overall score of "11" include 2-Naphthylamine [91-59-8], a known, potent bladder carcinogen at very low exposure levels. Also in this same scoring category are Ethylene Oxide [75-21-8] and Mustard Gas [505-60-2], both of which are extreme inhalation hazards in gaseous form. Also receiving a score of "11" is Warfarin [81-81-2], used as a rodent poison and anticoagulant. Using the WMPT scoring system, these chemicals receive the same score as Saccharin and salts [81-07-2], a compound which has been used as a non-nutritive sweetener human food additive for many years, with no significant adverse effects. (D76:6)

- Ethanol [64-17-5] is scored a higher risk than Methanol [67-56-1], which defies the fact that Methanol is more acutely toxic to mammals, has a significantly higher vapor pressure and is thus more volatile and readily released to the environment. This scoring also ignores the fact that Methanol has cumulative toxic effects in mammalian systems. (D76:6)

- All metals seem to be assigned a score of "13," regardless of any other defining information. It does not seem reasonable that Silver [7440-22-4] receives the same scores as Lead [7439-92-1]. (D76:6)

- The individual isomers of Xylene (ortho, meta, and para) each receive scores of "9," however the mixture of all three isomers, named "Xylenes" [1330-20-7], receives a score of "8." This simply does not make sense. (D76:6)

- Inconsistencies are found within the category with scores of "10." This group includes Acrolein [107-02-8], a severe irritant and sensitizer with other toxic effects; Aniline [62-53-3], exposures to which are known to induce methemoglobinemia in humans; Phosgene [75-44-5], a gas which induces severe pulmonary effects in humans at levels as low as 25 parts per million; and Vinyl Chloride [75-01-4], a gas that has been recognized and regulated as a carcinogen by the Occupational Safety and Health Administration (OSHA). Using the WMPT scoring system, these chemicals receive the same score as 3-Pyridinecarboxamide [98-92-0], otherwise known as Niacinamide or, more commonly, Vitamin B-3. Being placed in the category "10" scores also means that Vitamin B-3 is rated as a higher risk to human health and the environment than several OSHA carcinogens (including Acrylonitrile [107-13-1] and Formaldehyde [50-00-0]), Sodium Cyanide [143-33-9], Phenol [108-95-2], and Carbon Disulfide [75-15-0]. This erroneous conclusion has no basis in sound science. (D76:6,7)

- The WMPT methodology and the scores assigned to nickel should be corrected. Otherwise, nickel metal will be unjustly targeted as being of greater potential concern for waste minimization and enforcement purposes and will be wrongly viewed as presenting greater risks to consumers and industrial/commercial users than substances such as benzene (overall score of 12), mustard gas (overall score of 11), phosgene and vinyl chloride (overall score of 10), and cyanide (overall score of 9). The ranking of metallic nickel relative to these other substances in the Prioritized Chemical List illustrates the flaws in the WMPT and demonstrates the need either to revise the methodology or to shelve the project altogether. (D56:5)

- Notwithstanding the pitfalls of ranking chemicals using the WMPT, and the consequent potential misperceptions about risks associated with the chemicals listed in the draft PCL, EPA should take into account the possible ramifications of its ranking. In the case of copper, by labeling the metal as a substance bearing the same score as arsenic, and with a higher score than chloroform and mustard gas, users of copper may well be swayed to substitute away from it in many uses. One of copper's major uses is in plumbing where it holds around 85% of the US market. Plastic tubing in various forms supplies the balance of the US market. While copper has been used as a reliable material for water conveyance in the US for over 50 years, the longevity, and health effects of plastic are less well-known (concerns surrounding the use of plastic in water are summarized). While research on the above issues associated with plastic tubing is far from conclusive, the ramifications of large scale substitution to plastic should be considered when placing a relatively high risk ranking on copper. (D61:3)

- The ranking of sodium dichloroisocyanurate in the prioritization ranking process in the WMPT should be 6. (D59:6)

- EPA is urged to withdraw the PCL, or at least eliminate metals from the PCL. Also, EPA must provide appropriate limitations with respect to the WMPT's use with metals, such as a clear statement that score for the elemental metal should not be used to score metal compounds. (D43:i,7,19)

- EPA's prioritization is undermined in another way as well. In its attempt to be simple by including only a limited suite of parameters for chemical evaluation, EPA can cover only a limited number of substances evaluated by the WMPT. While close to 5000 chemicals are evaluated by the WMPT, only 900 show up on the DPCL because full data were available only for this number of substances. As a result some substances which should be targeted for waste minimization do not appear on the DPCL. (D61:2-3)

- The Pulp Chemicals Association is concerned by the WMPT relative ranking of four major components of the pulp chemicals industry. α- Pinene, ß- Pinene, Dipentene and Oleic Acid are constituents of turpentine or tall oil and are sold as products by members of the Pulp Chemicals Association. The List has them ranked with mustard gas, benzene and 2,4-D, reflecting the Pulp Chemicals Association's belief that there are fundamental flaws in the WMPT scoring system and of the List. The public perception of the industry and its products will be undeservedly negatively impacted by this EPA ranking and will lead to unnecessary regulations and misallocation of resources. It may also cause customers to avoid Pulp Chemicals Association products based on the relative ranking in the List. α- Pinene, ß-Pinene, and Dipentene are naturally occurring chemicals produced by coniferous trees. In the pure form, they are approved for use in human food. Oleic Acid is a naturally occurring fatty acid that is present in tall oil. Releases from the Pulp Chemicals Industry are minuscule in comparison to the quantities released naturally by our forests and there is no indication of damage to human health or the environment from natural or industrial sources. (D60:2)

- It is unclear why sodium dichloroisocyanurate is even evaluated on the PCL, since it is not listed as a constituent in even one waste code in "The Chemical-Waste Code Crosswalk" (EPA 530-D-97-003) that accompanied this draft waste management tool. Listing materials that EPA has not identified as a constituent of hazardous waste streams for minimization purposes seems an empty effort. (D59:3)

- On the draft Prioritized Chemical List (PCL), sodium dichloroisocyanurate is scored as medium persistence, low bioaccumulation potential, medium human toxicity and high ecological toxicity for a total score of 11 out of a possible 18. Sodium dichloroisocyanurate does not warrant a ranking above a score of 6, given its low potential to persist or bioaccumulate. Since it is specifically manufactured to provide a source of chlorine for sanitization, a score of 3 (high) for acute aquatic toxicity would not be surprising. However, the WMPT is alleged to be focused on chronic toxicity related to persistence and bioaccumulation, which should reduce this concern to low. We also believe that human toxicity should be scored lower, as should the persistence factor. Therefore, if sodium

dichloroisocyanurate is even considered in waste minimization using the WMPT (which we contest), its score should correctly be 6. (D59:3)

- The PCL should not include commercially viable products. Ranking of commercial products in the PCL for waste minimization considerations makes no sense. Chemicals manufactured as commercially viable products. e.g., pesticides, are not realistic candidates for waste minimization because they are not wastes. Manufacturers have sufficient incentives to ensure that every pound of the product being manufactured is available for commercial sale rather than lost as a process waste stream component. We, therefore, recommend that the PCL be limited to chemicals that are truly process wastes. (D69:4)

- The American Crop Protection Association questions the need and justification for the PCL. However, if EPA decides that such a list is justified due to regulatory and public communication needs, then we suggest that such a listing be: 1) based on a revised WMPT that more realistically reflects exposure scenarios to wastes in manufacturing and post-manufacturing environments; 2) limited to a smaller number of chemicals with higher data quality; and 3) applicable only to chemicals that are components of waste streams in manufacturing processes. (D69:4,5)

- The American Crop Protection Association believes that EPA's primary objective for the WMPT in public communications should be to improve awareness and understanding of risks from the various exposure scenarios associated to wastes during processing and waste treatment/disposal environments. The present draft PCL fails to achieve this objective since the significance of the risk perspective is lost in the arbitrarily ranking of chemicals by hazards. In addition to revising the PCL as recommended above, EPA could also provide an accompanying tutorial to the public on the difference between "hazards" and "risk." The tutorial could be developed around the simple formula: Hazard x Exposure = Risk. This formula correctly presents "hazard," i.e., the inherent properties of a chemical, and "exposure," i.e., the determining factor for a hazard to cause harm, as the components of risk. As in multiplication, if any multiplier is "0," then the product, i.e., "risk," is "0." (D69:5)

- The American Crop Protection Association recommends that registered pesticides be excluded from listing on the PCL. The basis for this recommendation is: 1) pesticides are commercially viable products, not wastes; 2) pesticides quantities in process waste streams are extremely low and extensively regulated; and 3) pesticides are extensively tested in accordance with FIFRA and evaluated by EPA for risks to humans and the environment to define safe and acceptable registered uses. (D69:6,7)

- We believe that the draft waste minimization prioritization tool (WMPT) and Prioritized Chemical List (PCL) are flawed because they provide a false impression of subtle, measurable differences among the 879 chemicals evaluated by using a quantitative scoring scheme. (D67:1)

- The inclusion of overall scores for all 879 PCL chemicals serves to undermine the Agency's caution that the WMPT provides only a relative ranking. The scoring, in fact, suggests that subtle quantitative differences between chemicals can be detected. Considering the significant variability in the quality and availability of data, it is entirely inappropriate to suggest that there are quantitative differences between many of the PCL chemicals. (D67:2)

- The ketones present a compelling example of compounds that should not be included at all in the WMPT or PCL, as available data clearly demonstrate that these chemicals should not be high, or even medium, priorities for waste minimization efforts, and should not be included in any program that purports to target persistent, bioaccumulative and toxic chemicals. (D17:3)

- Inclusion of methyl ethyl ketone and methyl isobutyl ketone in the WMPT is counterproductive, as these chemicals will be stigmatized and targeted for waste minimization efforts when in reality they pose low hazards to human

health and the environment and have many environmentally beneficial attributes. For example, methyl ethyl ketone and methyl isobutyl ketone can help reduce volatile organic compound (VOC) emissions from many coatings operations. These compounds also have been approved as substitutes for ozone depleting substances (ODSs) and can play a significant role in pollution prevention efforts in many industries. (D17:ii,20-24)

- EPA should remove ketones and other low toxicity, non-bioaccumulative, non-persistent chemicals from the WMPT to ensure that these chemicals are not perceived as "guilty by association" simply as a result of their inclusion in the WMPT and PCL. If EPA determines that chemicals such as methyl ethyl ketone and methyl isobutyl ketone need to be included in the WMPT, the Agency should ensure that it does so in a way that clearly indicates that these chemicals are a low priority for waste minimization activities. One approach would be to divide the draft PCL into tiers, with the first tier representing chemicals of high concern, the middle tier representing chemicals of moderate concern, and the third representing chemicals of low concern. Alternatively, EPA could create a "zero" score for chemicals that have low toxicity, low persistence or low bioaccumulation. Thus, a chemical could receive a score of zero for any individual element, which would demonstrate that it has low toxicity, or is non-persistent or non-bioaccumulative. Similarly, a chemical could receive an overall score of zero, demonstrating that it is non-PBT. By utilizing either one of these approaches, EPA could ensure that non-PBT, low-ranked chemicals such as ketones are not perceived as "guilty by association" simply as a result of their inclusion on the PCL. (D17:iii,26-27,28)

- EPA should change methyl isobutyl ketone's overall ranking on the WMPT and draft PCL to a "six." (D17:27)

- EPA should ensure that data are properly listed under the appropriate CASRN for Diiodecyl phthalate (DIDP) and Diisononyl phthalate (DINP); in some cases, it is not clear which CASRN, or whether a mixture of CASRNs, was tested. (D18:45, 48)

- EPA should remove acetone and other low-toxicity, non-bioaccumulative, non-persistent chemicals from the WMPT to avoid "guilt by association" that occurs simply as a result of their inclusion in the WMPT. (D14:ii,13)

- EPA should delete the entry labeled "phthalate" (CASRN 880357-00-0) from the WMPT; no such compound exists in isolation. (D18:4)

- EPA should correct an error in the listing of butyl cyclohexyl phthalate. This compound is listed under both CASRN 84-64-0 and CASRN 84-46-0; the latter CASRN is incorrect and should be deleted. (D18:4)

- EPA has used several different nomenclature conventions for naming phthalates in the WMPT; one convention should be chosen and used consistently. (D18:5)

- Methyl Chloride Industry Association believes that EPA should remove methyl chloride from listing under the WMPT and PCL. Over 99 percent of methyl chloride emissions are naturally occurring and come from such sources as oceans, forest fires, wood burning, coal burning, volcanoes, and fungal activity. Most of the industry-produced methyl chloride is consumed during use, such that the amount of methyl chloride available for waste minimization efforts is de minimis. Releases to air are trivial compared to natural sources. Releases to water quickly disappear due to rapid volatilization and biodegradation. Releases to land are, not surprisingly, essentially nonconsistent. Thus, methyl chloride should not be a high priority for waste minimization efforts. (D53:2)

- The PCL appears to be inappropriately weighted towards pesticides because there is extensive test data evaluating the health and environmental risks associated with the intended uses of these products. As a result, pesticides are an easy and compelling target for EPA to regulate under yet another statute even though the manufacture, handling, distribution, and use and disposal of these substances are heavily regulated under other statutory and regulatory schemes (e.g., CWA, RCRA, FIFRA, etc.). (D39:1-2)

- EPA should withdraw the phthalate esters from the WMPT until errors for these chemicals can be corrected (if the it does not withdraw the entire WMPT and PCL). The assigned scores (of 10 to 14) are inappropriately high despite the fact that most of the phthalate esters have low toxicity, low persistence, and low bioaccumulation potential; use of correct data would have resulted in scores of 6 or 7. (D18:i, 1, 2, 3, 9, 10, 16-17, 18, 20, 92)

- EPA should revise the total scores of specific phthalate esters. (D18:ia, 44) Specifically, using the WMPT methodology, scores should be changed for the following compounds:
  -Diiodecyl phthalate (DIDP), to 6. (D18:48)
  -Diisononyl phthalate (DINP), to 6. (D18:51)
  -Di-n-octyl phthalate (DnOP), to 6. (D18:55)
  -Di(2-ethylhexyl)phthalate (DEHP), to 6. (D18:62)
  -Butyl benzyl phthalate (BBP), to 7. (D18:70)
  -Dibutyl phthalate (DBP), to 7. (D18:74)
  -Diallyl phthalate (DAP), to 7. (D18:77)
  -Diethyl phthalate (DEP), to 6. (D18:81)
  -Phthalic anhydride (PA), to 6. (D18:86)
  -Di-(2-ethylhexyl)adipate (DEHA), to 6 or 7. (D18:90)

- If EPA determines that methyl chloride must be included in the WMPT, the Agency should ensure that it does so in a way that clearly indicates that methyl chloride is not a priority for waste minimization activities. One approach would be to expand the scoring scale, as suggested by Chemical Manufacturers Association and Silicones Environmental Health and Safety Council, to better distinguish between chemicals. In addition, EPA could divide the draft PCL into tiers, with the first tier representing chemicals of high concern, the middle tier representing chemicals of moderate concern, the third representing chemicals of low concern, and the fourth tier representing chemicals which should not be prioritized due to significant levels of naturally occurring emissions. Alternatively, EPA could create a "zero" score for chemicals that have low toxicity, low persistence or low bioaccumulation. Thus, a chemical could receive a score of zero for any individual element, which would demonstrate that it has low toxicity, or is nonpersistent or nonbioaccumulative. Similarly, a chemical could receive an overall score of zero, demonstrating that it is not a Persistent, Toxic or Bioaccumulative (PBT) chemical. Again, however, it is essential that EPA clearly indicate that methyl chloride should not be a priority for waste minimization efforts. By utilizing any of these approaches, EPA could ensure that non-PBT, low-ranked chemicals, such as methyl chloride, are not perceived as "guilty by association" simply as a result of their inclusion on the PCL. More importantly, by identifying the appropriate prioritization, the Agency will better ensure that waste minimization efforts are directed at chemicals that can achieve real overall reductions. As complete elimination of industrial sources of methyl chloride would have no meaningful impact on the overall level of methyl chloride in the environment, scarce Agency, state and private resources should not be diverted from other chemicals for which meaningful waste minimization goals can be achieved. By removing some of the chemicals from the list or identifying low or no priorities for concern, EPA and emitters will be able to more meaningfully and effectively focus on efforts that will achieve waste minimization goals. (D53:6)

- The six ethylene glycol ethers on the draft PCL are not among the chemicals the WMPT was designed to identify. (D45:2)

- The WMPT might be misused to compare glycol ethers to other chemicals that have lower scores. (D45:2)

- Only scoring chemicals with full data sets unfairly penalizes groups that have spent millions of dollars to make sure their chemicals are fully tested, often in cooperation with EPA. (D45:2)

- One commenter states that the OCS for dicofol drops from 17 to 15 when the observed data rather than the modeled data are used in estimating log K_{ow} for the bioaccumulation score. Also the human toxicity score was based upon structure-activity relationships even though ample toxicity data has been submitted to EPA on the chronic and subchronic toxicity to mammals. Nevertheless, the human toxicity ranking using structure-activity relationships would not have been changed by the use of measure toxicity data for this chemical. (D34:5)

- One commenter states that the OCS for 2-n-octyl-4-isothiazolin-3-one, a biocide, EPA used modeled data in estimating the human toxicity score instead of available observed data. In particular, for human toxicity, WMPT used the Chemical Class Human Toxicity Estimate, a structure-activity relationship yielding a human toxicity score of 3. Using a rodent sub-chronic NOEL = 20 mg/kg would yield a human toxicity of 2. (D34:5)

- IPBC, 3-idio-2-propynyl butyl carbamate, should not be listed in the waste minimization prioritization. It makes little sense to list IPBC as a priority for waste minimization when there is very little waste IPBC at all. IPBC is a product, rather than a feedstock or byproduct. It is used in small quantities in such applications as paint and wood preservatives. These down streams do not react IPBC, they simply mix it into their processes. There is little or no waste from these formulators. (D44:2-3)

- EPA states in the WMPT that additional factors not considered affect persistence, bioaccumulation, and toxicity. Publishing a ranked list of chemicals based on incomplete and sometimes incorrect data will only serve to undermine the original intent of the program by focusing on the wrong materials. (D36:i)

- Direct Black 38 does not belong on the list because it is a benzidine-based dye and is covered by EPA's SNUR for benzidine-based chemical substances which was promulgated in October 1996. Under the provisions of that SNUR, any future manufacture or use of Direct Black 38 is prohibited without notification to EPA. (D41:2)

- The composite score of 16 for 4,4'-methylenediphenyl diisocyanate (4,4'-MDI) greatly overstates the potential persistence, bioaccumulation and toxicity of this compound. The rapid reactivity of 4,4'-MDI with water to form predominantly inert polyurea products and available health and environmental toxicity studies support a score of 7. (D19:i,2,4)

- EPA calculated composite persistence, bioaccumulation and toxicity scores of 13 for toluene diisocyanate (TDI) (commercial) and 2,6-TDI and 12 for 2,4-TDI. Commercial TDI is approximately an 80:20 mixture of 2,4-TDI and 2,6-TDI. The 2,4- and 2,6-TDI isomers, by themselves, are not commercially viable products. The commenter therefore recommends that the listings for the TDI isomers be evaluated together as generic or commercial TDI and assigned CASRN 2647-62-5. This description and CASRN include all mixtures of the 2,4-TDI and 2,6-TDI isomers. (D19:9)

- For toluene diisocyanate (TDI) and the 2,6- and 2,4-TDI isomers, a composite score of 8 is supported by available information, including the rapid reactivity of the isocyanate group with water and the health and environmental toxicity data for these compounds. (D19:ii,3,10)

- The Draft Priority List identifies two CASRNs for nonylphenol (NP): 25154-52-3, which designates a non-commercial straight chain compound, and 84852-15-3, a commercially relevant para (or 4-) branched NP material. The Draft PCL identifies NPE using CASRN 901645-9. This listing describes the commercial, branched nonylphenol polyethoxylate. The listing does not specify the position or degree of ethoxylation or the branching of the alkyl chain. Other essentially equivalent NPE descriptions for commercial products include polyethoxylated (isononylphenol) (CASRN 37205-87-1); polyethoxylated (nonylphenyl) (branched) (CASRN 68412-54-4), polyethoxylated (4-nonylphenyl) (branched) (CASRN 127087-87-0) and α-(4 nonylphenyl)-ω-hydroxy-poly(oxy-1,2-ethanediyl) (CASRN 26027-38-3). (D20:4)

- There are a number of commercial octylphenol (OP) and octylphenol ethoxylate (OPE) products. For OP, these include 4-(1,1,3,3-tetramethylbutyl)-phenol (CASRN 140-66-9), which is listed on the draft PCL, and 4-octylphenol (CASRN 1806-26-4) and (1,1,3,3-tetramethylbutyl) phenol mixed isomers (CASRN 27193-28-8), which were not. Commercial OPE includes polyethylene glycol mono (octyl) phenyl ether (CASRN 9036-19-5), which was included on the draft PCL. Other OPE products are polyethoxylated (octylphenol) (branched) (CASRN 68987-90-6); polyethoxylated (isooctylphenyl) (CASRN 9004-87-9) and polyethoxylated (octylphenyl) (CASRN 9063-89-2). These OPEs were not included on the draft PCL. (D20:4)

- Oxo process chemicals are compounds that should not be included at all in the WMPT or PCL, as available data clearly demonstrate that these chemicals should not be high, or even medium, priorities for waste minimization efforts, and should not be included in any program that purports to target persistent, bioaccumulative and toxic chemicals. All of the oxo process chemicals are examples of compounds that should and would drop out of the WMPT program if EPA were to adopt Chemical Manufacturers Association's recommendation for zero-based scoring. (D25:3)

- Oxo process chemicals have low toxicity and are nonpersistent and nonbioaccumulative. These chemicals are widely used industrial solvents and chemical intermediates. (D25:16)

- Because of their low toxicity and wide variety of uses, oxo process chemicals can play a significant role in the pollution prevention efforts of many industries. The listing of oxo process chemicals in the WMPT serves no useful purpose, and may actually discourage pollution prevention efforts by inappropriately conveying the impression that emissions of these chemicals, simply because they are on a list of "PBTs," pose significant environmental hazards. There is no scientific or environmental basis to suggest that these chemicals should be considered a high priority for waste minimization efforts. Accordingly, to avoid discouraging companies from identifying environmentally beneficial uses of oxo process chemicals, the Oxo Process Panel believes these chemicals should simply be removed from the WMPT and PCL. (D25:17)

- Oxo Process chemicals clearly are not a high, or even a medium, priority for waste minimization activities. Unfortunately, however, the WMPT could have exactly the opposite effect because under EPA's existing scoring system, the mere fact of inclusion on the WMPT, and, more particularly, the draft PCL, results in a chemical being considered PBT. Even chemicals that receive an overall score of six will be considered PBT simply because they are included on an EPA-endorsed list of PBT chemicals. The Panel therefore recommends that EPA simply remove all oxo process chemicals and other low toxicity, nonpersistent, nonbioaccumulative chemicals from the WMPT, or, at a minimum, the PCL. Instead, EPA should include only a selected few (e.g., 20) of the most PBT chemicals in its draft PCL, and simply not rank the remaining chemicals in the WMPT. In this way, EPA can ensure that the many "non-PBT" or "less-PBT" chemicals are not stigmatized by the few truly PBT chemicals, merely by inclusion in the WMPT and PCL. (D25:ii, 19)

- The Panel believes that EPA should change butanol's overall ranking on the WMPT and draft PCL to a "six." (D25:20)

- EPA should revise the WMPT so that low toxicity, nonpersistent, nonbioaccumulative chemicals such as oxo process chemicals are not targeted simply because they are used or released in large volumes. The simplest approach would be to remove these chemicals from the WMPT and the PCL. (D25:20)

- Hydrocarbon solvents are degradable and none are bioaccumulative. Thus, the WMPT is not needed to determine whether the hydrocarbon solvents should be included among the persistent, bioaccumulative and toxic chemicals EPA sought to identify. (D24:1)

- The draft PCL optimizes the flaws in the WMPT as a relative risk screening tool. (D49:cover,20)

- The draft PCL scoring derived by application of the draft WMPT model of octamethylcyclotetrasiloxane (OMCTS) and trichlorophenylsilane—suffer from serious inaccuracies. (D49:cover)

- Draft PCL scoring does not reflect relative PBT risks in any sense given that the draft PCL was created omitting the mass component of the draft WMPT model. Chemicals identified on the PCL will be targeted for reductions and these reductions will be used to assess progress towards achieving waste minimization. Without including the mass component of the WMPT so that the scoring reflect relative risk, however, the acknowledged "starting point" for identifying priority chemicals will become the end point and waste reduction efforts will fail to achieve meaningful reductions (D49:cover, 4, 20-21)

- The PCL is characterized by an unknown degree of scientific uncertainty. EPA cannot say with any confidence that reductions in use of the first 100 chemicals on the PCL achieve the goals of the Pollution Prevention Act or Waste Minimization National Plan to any greater degree than a similar reduction in the last 100 chemicals. Those who use the PCL as a stand-alone tool will be completely unaware of the uncertainty inherent in the chemical rankings. (D31:3,4)

- EPA should not develop a PCL based on WMPT. (D29:cover1)

- The WMPT has been used to generate the PCL even though the WMPT lack key features essential for risk analysis. The PCL establishes a list of PBT chemicals without considering factors that determine a chemical's absolute or relative hazard. (D27:ii,18)

- The lack of a zero score for chemicals on the PCL gives the appearance that all chemicals on it are PBTs; this is not the case. (D27:iii, 57-58)

- The Draft PCL is the worst piece of simplistic pseudo science produced since EPA's inception. (D5:1)

- The draft PCL could be divided into tiers, with the first tier representing chemicals of high concern, the middle tier representing chemicals of moderate concern, and the third representing chemicals of low concern. This would clearly indicate that acetone is a low-priority for waste minimization activities. (D14:13-14)

- Different states and regions already have their own ways of prioritizing wastes and chemicals, and these may differ from those used to derive the PBT-based PCL. The states and regions should be polled, and they could submit a list of their priority waste streams or industries. OSW then could use the cross-walk to "backtrack" from waste streams or industries to determine which chemicals should be of priority based on the state and regional input. This will also help with the measurement effort because OSW will be focusing on PBT chemicals that are already being targeted by the states and regions. (T1:2)

- Some chemicals on the PCL are not hazardous waste issues (e.g., mercury), and there is not a clear distinction between solid and hazardous waste in regulatory issues. There is also a trend toward blurring the distinction between hazardous and solid wastes. (T1:4)

- The PCL scores do not include mass data. When mass data are added to the tool by individual users, the rankings will change. This could cause confusion among different users. In addition, the PCL, on its own, may be used for unintended purposes. Therefore, the PCL, without mass data, should not be published as a separate document; however, it is acceptable to distribute the PCL with the tool. (S1s:29,32)

- Hydroquinone and IPA are examples of compounds that should not be included at all in the WMPT or PCL, as available data clearly demonstrate that hydroquinone and IPA should not be a high, or even a medium, priority for

waste minimization efforts, and should not be included in any program that purports to target persistent, bioaccumulative, and toxic chemicals. Having a subset of 800 chemicals on a waste minimization list merely because these are the ones with sufficient data for ranking invites stigmatization of the chemical and misuse of the list. There are at least 50,000 chemicals not on the list that might be more toxic, persistent, and bioaccumulative than the listed chemicals. (D26:ii,3,4; D16:3)

- Based on an initial review, the Hydroquinone Panel believes at least half of the chemicals on the draft PCL are of low concern for health and environmental risk potential. Inclusion of these chemicals on the PCL would stigmatize them merely because they are high volume chemicals for which extensive information has been generated over the years. If EPA wants to encourage people to move away from more hazardous chemicals to less hazardous chemicals, the Agency is working against this objective by stigmatizing the high production volume, low hazard chemicals on the list. Any chemical that industry is encouraged to use because of low hazard will tend to move toward higher volume and become a stigmatized target for waste minimization. Eliminating any mass component from the prioritization section is one way to solve this problem. Another solution is to remove hydroquinone and other low hazard compounds from the PCL. (D26:10,11)

- Hydroquinone clearly should not be a high priority for waste minimization activities. Unfortunately, the mere fact of inclusion on the WMPT, and, more particularly, the draft PCL, may result in a chemical being considered PBT. Even chemicals like hydroquinone that receive a low score may be considered PBT simply because they are included on an EPA-endorsed list of chemicals that purports to identify PBTs. The Panel, therefore, recommends that EPA simply remove hydroquinone and other low toxicity, non-persistent, non-bioaccumulative chemicals from the WMPT, or, at a minimum, the PCL. Instead, EPA should include only a selected few of the most PBT chemicals in its draft PCL, and simply not rank the remaining chemicals in the WMPT. In this way, EPA can ensure that chemicals such as hydroquinone are not stigmatized by the mere inclusion in the WMPT and PCL. If EPA determines that chemicals such as hydroquinone need to be included in the WMPT, the Agency should ensure that it does so in a way that clearly indicates that hydroquinone is a low priority for waste minimization activities. The Panel suggests, for instance, that EPA modify its scoring system to allow for a "zero" score for chemicals that have low toxicity, low persistence, or low bioaccumulation. Under this approach, a chemical could receive a score of zero for any individual element, which would demonstrate that it has low toxicity, is non-persistent, or is non-bioaccumulative. Similarly, a chemical could receive an overall score of zero, demonstrating that it is non-PBT. As yet another possibility, EPA could eliminate from the WMPT and PCL all chemicals that are neither persistent nor bioaccumulative, or that are released in quantities that are too small to pose significant hazards to human health or the environment. This approach would appropriately direct attention to those chemicals that pose the greatest concern for chronic hazards, whether pertaining to human health or ecotoxicity. By utilizing any one of these suggested approaches, EPA could ensure that non-PBT, low-ranked chemicals, such as hydroquinone, are not perceived as "guilty by association" simply as a result of their inclusion on the PCL. (D26:11,12)

- EPA should change hydroquinone's overall ranking on the draft Prioritized Chemical List to a "seven." The Panel further requests that EPA revise the WMPT so that low hazard chemicals such as hydroquinone are not targeted simply because they are used or released in large volumes. The simplest approach would be to remove hydroquinone and similar compounds from the WMPT and PCL. (D26:i,12)

- Analysis, by Silicones Environmental Health and Safety Council, of the scoring for two silicones contained in the draft PCL demonstrate the flaws of the draft WMPT. The draft PCL constitutes a misuse of WMPT because it fails to include the mass component of the model, and thus, the draft PCL scoring do not reflect relative risks. As a major producer of octamethylcyclotetrasiloxane (OMCTS), GES is quite concerned that the draft PCL could be seriously misleading to regulators in Europe and Japan, and be seriously misinterpreted by US environmentalists. The draft PCL should be withdrawn by EPA. (D52:1)

- One option to consider is to publish the PCL showing the values given to each chemical ordered alphabetically or by CAS number. (D55:7)

- The listing of silver as a toxic chemical in the proposed PCL is completely spurious and misleading. Its use by the public would be a hazard to the significant US industry built upon the healthful sanitation properties of silver. Even to have silver listed in such a list of "toxic chemicals" would be a signal to the uninformed that silver is a hazard and should be avoided. We note that chlorine is not even listed though it has been linked with the formation of cancer for over a generation (See: Chlorination, Chlorination By-products, and Cancer, R.D. Morris, et al, American Journal of Public Health, July, 1992, p. 955). The chlorine industry as well as other interests could use the proposed PCL to commercial advantage. The chemicals listed are distinct entities, each with unique properties demanding specific treatment in a waste stream. No environmental chemist would consider the PCL as being of any value in assessing the hazards of specific waste streams, nor would they find it useful in the required treatment or removal of those hazards. To lump silver, a healthful element with unique sanitation properties with unmatched healthful epidemiological data, in a collection of seriously hazardous chemicals is evidence of a lack of knowledge of the chemistry of this unique metal. Silver does not belong in this list at all. (D51:4,5)

II. Potential Applications of the Waste Minimization Prioritization Tool

A. Need for Review, Transparency, and Updates

- WMPT 1.0 needs to be improved markedly before it will be used on a regular basis by these industry participants. (P1:23)

- A transparent public process is necessary to ensure that any application of the WMPT to screen a particular chemical relies on sound, current data. (D49:cover)

- Create a formal public process for application of the WMPT which mandates that (I) reliable and accurate data available to the public is used and (ii) revisions to the WMPT scorings based on new or more accurate data can occur upon the petition of an interested stakeholder. (D49:cover, 29)

- Given that there are many intended users of WMPT, it is important that WMPT be completely transparent and its output simple to interpret and use. A preliminary screening tool should allow interested parties to direct their immediate attention to the substances that pose the most and least risk (or that possess the highest and lowest intrinsic hazard). Then, risk managers can direct their activities towards decreasing, substituting, or encouraging the use of products and processes to provide an overall "cleaner" effluent stream. Therefore, chemicals within each "rank" should be of approximately equal risk. Within the constraints imposed on any system that is an effective continuum of toxicity and exposure, there should be the capacity to distinguish between "ranks." (D29:4)

- Given that the WMPT and PCL address significant issues which could have a broad impact on small businesses, EPA should honor the spirit and intent of SBREFA by specifically seeking comment from potentially affected small entities regarding the potential impact of the WMPT and PCL. EPA should establish a small business review group comparable to a "SBREFA small entity review panel" for the WMPT and the Priority List. (D40:11)

- If the WMPT is not abandoned, it should be revised and/or postponed in order to conduct a comprehensive review of both the policy decisions and the scientific basis for the current draft. This review must consider both scientific validity as well as the impact of the tool on small companies and facilities. (D40:1, 11)

B. General Pleas to Withdraw the WMPT

- EPA should withdraw the WMPT, due to its errors and the assumptions about which typical users may be unaware. (D24:3)

- The WMPT is so pervasively flawed that EPA should withdraw it and its product, the draft Prioritized Chemical List (PCL). (D21:5)

- One commenter urges EPA to withdraw the PCL because of doubts concerning the validity of the data and rankings generated by the WMPT. (D38:1)

- We are vitally interested in this RCRA action under development by EPA because of its precedent-setting impacts beyond the scope of RCRA and the potential for affecting pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The American Crop Protection Association supports the concept and basic intent of the WMPT. We agree that with better information EPA, the public, and industry alike are able to make more informed decisions for implementing effective and prudent waste minimization strategies. However, a fundamental principle behind this is the requirement that the information available to decision makers be based on sound science and realistically represent those risks associated with waste exposure scenarios, e.g., manufacturing operations, reuse/recycle, transportation, or disposal. Our primary concern with the current version of the WMPT is that it does not follow this principle. As drafted, the WMPT is seriously flawed and will not achieve EPA's intended waste minimization objectives. In fact, the resulting ranking of chemicals could be counterproductive to existing industry waste minimization programs. (D69:1)

- The WMPT is not a tool that will be useful for its intended purpose. While Reilly appreciates and commends EPA on its non-regulatory approach to waste minimization, we believe that the WMPT, as currently offered, is an inflexible, ineffectual, and error-laden system. (D76:7)

- EPA should reconsider its use and release of the Draft Waste Minimization Prioritization Tool and Draft Prioritized Chemical List. (D48:23)

- An appropriate risk-based waste minimization prioritization tool could be useful to us, and we have followed the development of this tool with interest. However, after much review, we do not believe that the WMPT, in its current state, would be useful to our waste minimization efforts. Likewise, we do not believe this tool would further the cause of waste minimization across the chemical industry. (D76:1)

- EPA is urged to withdraw the WMPT and its products, particularly the PCL. If EPA declines to withdraw the WMPT, EPA should eliminate metals from the WMPT. At the very least, EPA must provide appropriate limitations with respect to the WMPT's use for metals. (D43:i)

- EPA should withdraw the WMPT and its products because they are fundamentally flawed. The WMPT and the draft PCL will not further EPA's goals of effective waste minimization, or help businesses or other users plan for or implement effective pollution prevention programs. Moreover, they will have significant, unfair, and baseless adverse consequences for metals and many other chemicals that they incorrectly and inaccurately characterize, in contexts far removed from waste minimization—such as permitting decisions, enforcement activities, other regulatory actions, and product selection and deselection. (D43:2)

- The Antimony Oxide Industry Association supports EPA's efforts to develop a risk-based tool that can be used by facilities to help determine priorities for waste minimization efforts. However, like the Chemical Manufacturers Association and other industry groups that have submitted comments, the Antimony Oxide Industry Association

believes the proposed WMPT and PCL contain significant methodological and technical flaws, such that these tools are not likely to be useful to the intended users. (D66:2)

- The Methacrylate Producers Association, Inc. (MPA), urges EPA to limit strictly any use of the Waste Minimization Prioritization Tool (WMPT). The WMPT software contains substantial unverified information on, and potentially misleading relative rankings of, thousands of chemicals. MPA is very concerned that the information and rankings, including the Prioritized Chemical List, will be misused to evaluate and compare chemicals for a wide variety of purposes unrelated to EPA's waste minimization goals. EPA lists often take on a life of their own and are employed for purposes never intended by their authors. The best means of preventing such undesirable consequences here would be for EPA to withdraw the WMPT. (D62:1)

- It is likely that the WMPT will be used in a manner that makes it much more than a tool for finding the most persistent, bioaccumulative and toxic chemicals in hazardous waste. The Agency has widely circulated the software and all the information it has compiled on thousands of chemicals. As a result, information whose accuracy is not uniformly good and cannot always be confirmed and whose import is likely to be misinterpreted has become widely available under an EPA imprimatur. Moreover, inaccurate information is in the database. Unless all errors are corrected (and the database updated as new information becomes available), the software should now be retired. (D62:2)

- Although the ranked ketones all received generally favorable scores, the commenter believes that the flaws and deficiencies in the proposed WMPT are so numerous and fundamental that EPA should not go forward with the WMPT in its current form. (D17:i,2)

- In Appendix A, EPA has relegated a statement which we strongly believe accurately describes the serious limitations of the Tool for actual use in a site-specific risk context, and underscores the lack of value of the Tool and the List for the site environmental manager: Use of WMPT does not constitute a risk assessment. The PBT scores reflect inherent hazard only and, other than the mass of the chemical, WMPT does not incorporate any site- or situation-specific factors in its scoring approach. The necessary simplifications that have been incorporated in WMPT make it unlikely that this scoring approach would be fully consistent with rankings developed based on in-depth risk assessment. (Appendix A, p. A-1 2 to -1 3). Both the WMPT and the Priority List fail to address key questions involved in the management of waste at facilities, such as: (1) Are the chemicals being discharged in sufficient concentrations in waste streams to pose an unacceptable risk to humans or the environment, on or off the plant-site?; (2) What chemicals being released are essential to production and irreplaceable? Are their risks being properly managed? (3) Which chemicals are peripheral to the primary production process? Of these, are there cost-effective substitutes available with more desirable characteristics? (4) What is the efficacy of the compound in the industrial manufacturing operation? Could potential alternatives be used at similar or reduced volumes, or would substantially more of another waste be generated? (5) Where are wastes being generated? In what waste stream and form? What is the duration, frequency, and concentration? and (6) Once safety concerns are addressed, how can additional waste reduction be maximized for the cost? (D30:5-6)

- The Methyl Chloride Industry Association (MCIA) believes the WMPT as proposed is fundamentally flawed. Because of these flaws, MCIA believes the WMPT will not further EPA's goals of waste minimization, or help businesses or other users plan for or implement effective pollution prevention programs. (D53:2)

- The use of the Software as a prioritization tool for waste minimization activities encourages a simplistic analysis which may not accurately reflect the hazards posed by manufacturing use and the volume of the targeted substance in commerce. (D12:3)

- The WMPT should not be relied upon until the Agency develops and implements a system for correcting the inaccurate and outdated data contained in the tool. Without such a correction mechanism, the WMPT software should immediately be withdrawn from circulation. (D45:1,4)

- The flaws and deficiencies in the proposed WMPT are so numerous and fundamental that EPA should not go forward with the WMPT in its current form. (D21:4-5; D25:4-5)

- WMPT suffers from serious methodological flaws that prevent it from being a legitimate vehicle to screen chemicals on a relative risk basis. These include: (I) an incomplete characterization of environmental fate; (ii) an inaccurate "high quality" data component, (iii) an inadequate scoring approach, and (iv) an invalid exposure component. (D49:cover)

- API supports the Agency's development of a tool that can be used by individual facilities to help prioritize their waste minimization efforts. However, API has significant concerns regarding the implementation of WMPT. (D29:cover1)

- Although IPC supports the concept of a tool that would provide industrial facilities with information regarding the relative environmental risks of the chemicals they use, IPC opposes continued development of WMPT in its current form. Specifically, IPC opposes WMPT because it lacks a sound, scientific basis and, as a result, will not inform potential users of the true environmental risks posed by listed chemicals. (D54:1)

- Because WMPT oversimplifies the concept of calculating environmental risk and utilizes erroneous assumptions about persistence, bioaccumulative effects, and toxicity, the tool results in irrational results. For example, methylene chloride is considered a suspected human carcinogen, yet it is ranked as a 2 for human toxicity. The draft software ranks diazinon, nickel, and cadmium slightly higher than copper, which in turn is ranked the same as lead, arsenic, and chromium. These are all ranked higher than benzene (a potent carcinogen), mustard gas, cyanide, and toluene. Cyclohexanone, formic acid, and methanol are ranked at the bottom of the list with *table salt!* Because of these erroneous and ludicrous results, WMPT is doomed to fail as a screening tool for comparing chemical's respective environmental risks, or worse, if it is used, it will be misused. (D54:3)

- EPA's Waste Minimization Prioritization Tool will be used to promote regulatory or non-regulatory chemical use reduction and/or elimination efforts that are not based on sound science. (D54:3)

- IPC does not oppose the concept of WMPT. In fact, we support the development of an accurate, reliable, and up-to-date chemical ranking tool that would enable our member companies to make informed judgments regarding pollution prevention options. IPC urges EPA to withdraw WMPT, its products, and its list. If EPA continues to develop WMPT, EPA should ensure that the tool is subject to all regulatory procedures since, once developed, WMPT will take on a life of its own and be used to support future regulatory actions. (D54:4)

- The WMPT and PCL should be withdrawn altogether due to the many flaws that exist. Unless formally withdrawn, EPA offices, state agencies, and other organizations will use a draft list or tool until a revision is provided; since a revision cannot be provided, it should be withdrawn. (D18:i, 19, 20, 35)

- The WMPT and the PCL are unfit tools for making major waste minimization decisions. EPA needs to clarify the severe limitations in the methodology and data underlying the WMPT and the Priority List and emphasize that they should not be relied upon as a primary factor in waste minimization decisions. Instead, site-specific risk assessments should be used. (D40:2)

- A crude hazard ranking tool like the WMPT is of low value. In particular, smaller companies and smaller facilities would benefit from more specific information on waste minimization methodologies, options, opportunities and success stories. This is particularly true for batch processors. (D40:2)

- The shortcomings of the WMPT and Draft PCL (e.g., not assessing the individual valence states for each metal) will result in misidentification of those substances that truly present significant threats to human health and the environment, will cause EPA to waste risk-reduction resources, and will destroy the credibility of EPA's efforts. For example, the Draft PCL will encourage steel facilities to direct resources at reducing the use of benign forms of nickel and chromium instead of 1,1,1-trichloroethane (score 11), a substance that has been the subject of earnest minimization activities for years. (D9:5; D10:5)

- Although the development of a risk-based tool that can be used by facilities to help determine priorities for waste minimization efforts is a worthwhile goal, the flaws and deficiencies in the proposed WMPT are so numerous and fundamental that EPA should not go forward with the WMPT in its current form. (D14:i,2)

- Like the Chemical Manufacturers Association and the Chlorine Chemistry Council (CCC), the Hydroquinone Panel supports waste minimization objectives and believes that development of a voluntary, flexible risk-based tool that can be used by facilities to help determine priorities for waste minimization efforts is a worthwhile goal. However, the Hydroquinone Panel also shares the strong concerns expressed in the comments prepared by Chemical Manufacturers Association and CCC, and believes that the flaws and deficiencies in the proposed WMPT are so numerous and fundamental that EPA should not go forward with WMPT in its current form. (D26:3)

- Like the Chemical Manufacturers Association and the Chlorine Chemistry Council (CCC), the Isopropanol Panel generally supports waste minimization objectives and believes that development of a risk-based tool that can be used by facilities to help determine priorities for waste minimization efforts is a worthwhile goal. However, the Isopropanol Panel also shares the strong concerns expressed in the comments prepared by Chemical Manufacturers Association and CCC, and believes that the flaws and deficiencies in the proposed WMPT are so numerous and fundamental that EPA should not go forward with the WMPT in its current form. (D16:3)

- The Cement Kiln Recycling Coalition's (CKRC) members have a significant interest in the development of information and implementation of efforts to minimize and manage wastes according to the priorities established by the national waste management hierarchy. While CKRC supports Agency efforts to assist waste generators with their waste minimization efforts using scientifically based tools or approaches, CKRC raises several general concerns regarding EPA's current efforts to develop waste minimization prioritization tools. (D57:1,2)

- Unless remedied, the current flaws in the WMPT software will result in inaccurate scorings and reliance on data that may lead to unintended and potentially damaging or counterproductive results. (D49:4)

- The draft Tool and draft Priority List are sufficiently flawed and should be withdrawn by the Agency. (D30:2)

- The WMPT is duplicative of other EPA efforts and therefore contrary to the Common Sense Initiative and its aims of cleaner, cheaper, and smarter regulation. (D9:2)

C. General Support for the WMPT

- There was a strong consensus from the facilities participants that the WMPT is a useful program and the EPA should continue to develop it. Its greatest asset is the extensive database of persistence, bioaccumulation and toxicity (PBT) information and the collation of federal waste codes. All participants believed that it was a very powerful reference document. The most used feature of the WMPT was the PBT ranking of chemicals. Having the RCRA waste code information centralized in a single computer program was also highly desirable. In fact, several participants asked whether these lists could be printed as a hard copy. Many of the participants appreciated what they perceived as a change in the EPA's focus of hazardous waste reduction from regulation to using environmental and toxicological principles, such as PBT. The comments regarding the use of the WMPT by the facilities participants centered on getting information on replacement chemicals rather than questioning its inherent usefulness or scoring. The participants believed and accepted the PBT ranking without much questioning. They were more concerned with what replacement options were available for chemicals with high PBT scores. The high-tech industry generates very specific hazardous waste. Many of the chemicals are ones that cannot be replaced without changing their present manufacturing processes. (P1:7,17,18)

- We hope EPA will improve this tool and produce other environmental evaluation tools. (P1:10)

- There is great value in increasing the focus of RCRA waste minimization on the toxic reduction portion rather than just reductions in waste volume. (D55:cover3)

- WMPT should maintain a waste minimization and pollution prevention focus. As evidenced by the high cost and difficulty of cleaning up PBT chemicals, waste minimization and pollution prevention are the most cost efficient and effective approaches to avoiding future liabilities. (D55:9)

- Waste minimization and the use of tools related to waste minimization are useful strategies for industry. (D27:3)

- The WMPT is a very useful tool. It allows a broad view of environmental hazards to be taken. Having so many chemicals evaluated for the same criteria (PBT) and on the same database is very helpful. (P1:10, 20)

- While all of the facilities had initiatives in place to reduce hazardous waste, the WMPT was the only tool that the participants knew about to assist in pollution prevention efforts. In general, the participating companies are concerned with between 10 and 30 chemicals in their waste stream. The chemicals of concern were those with regulatory requirements. Mass weighted ranking of chemicals was useful, but predictable for many participants. (P1:18,19)

- The WMPT is potentially a very useful tool. At this time though, it does not appear to be very beneficial for our organization. (P1: A-2)

- Development of a risk-based tool that can be used by facilities to help determine priorities for waste minimization efforts is a worthwhile goal. (D21:4; D25:4)

- The WMPT possesses some favorable qualities that may assist facilities in waste minimization. (D27:9)

- A tool such as WMPT will be useful or very useful. A risk-screening system for chemicals will supplement existing tools and/or methods (e.g., for site assessment for cleanup). (T2:1)

- Of the participants at the Midwest Pollution Prevention Conference that filled out customer feedback surveys, four found the system as a whole “very useful,” while three found it “useful.” Similarly, regarding the scoring of chemicals based on PBT, four found it “very useful,” and three found it “useful.” (T3:2)

- Nine (9) of the respondents at the National Pollution Prevention Roundtable who completed customer feedback questionnaires believed the system as a whole was "very useful," while the remaining two (2) believed it was "useful." Six (6) of the respondents believed that the tool would be "very useful" in scoring chemicals based on PBT, occurrence in RCRA wastes, and by media specific concerns. (T5:2)

- The Tool is an excellent program for the government and private sector use. (T5:4)

- The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) group that reviewed WMPT supports the general concept of development of a screening tool for waste minimization and believes it can be useful to State programs. The WMPT appears to be a good start in developing a tool that can help EPA, State programs, and others identify priorities for waste minimization and toxics reduction. (D55:cover1)

- WMPT should continue to focus on waste minimization and pollution prevention (i.e., providing a proactive tool) and voluntary initiatives. (D55:cover3)

- Reilly would like to stress the willingness of industry to work with EPA in the development of such tools in the future. We believe that stakeholders meetings held early in the tool's development would have brought these major flaws to light well in advance of committing the significant effort and resources that EPA has obviously invested in the development of this tool. We continue to stress our belief that waste minimization and pollution prevention efforts should be recognized as continuous improvement efforts, rather than the process of waste minimization being viewed as an end unto itself. (D76:7,8)